Journal of
CHRONIC
DISEASES

VOLUME 14 . NUMBER 6

DECEMBER, 1961

ol. 14
1961

Cancer

THE EFFECT OF CHEMOTHERAPY ON ACUTE LEUKEMIA IN THE HUMAN

EMIL J FREIREICH, M.D.,
EDMUND A. GEHAN, PH.D.,
DAVID SULMAN, M.D.,*
DANE R. BOGGS, M.D.,**
AND EMIL FREI, III, M.D.

BETHESDA, MD.

From the Chemotherapy Service, General Medicine Branch, National Cancer Institute, National Institutes of Health

(Received for publication March 20, 1961)

THE natural history of acute leukemia in humans has been significantly altered since the introduction of effective chemotherapy in 1949.[1] Three classes of chemotherapeutic agents are capable of inducing remissions of the disease: antipurines, antifolics, and adrenal steroids.[2] As a result, the fulminant and rapidly fatal course of untreated acute leukemia has changed to a more chronic course associated with temporary remissions of the disease. The successful use of these agents has spurred the search for new chemotherapeutic agents. The purpose of this study is to present certain aspects of the clinical course of acute leukemia treated with the available chemotherapeutic agents. In addition to documenting the alterations in the disease resulting from that therapy, these data can be useful for comparison with data accumulated in the future when newer forms of therapy are available.

MATERIALS AND METHODS

Case Material.—during the 5 year period between Oct. 23, 1953, and Oct. 20, 1958, 178 patients with an established diagnosis of acute leukemia were

*Present address: Department of Medicine, University Hospital, University of Maryland, Baltimore, Md.

**Present address: Department of Medicine, University of Utah College of Medicine, Salt Lake City, Utah.

admitted to the Chemotherapy Service of the National Cancer Institute. Diagnoses were confirmed by examination of supravital and fixed stained preparations of aspirated bone marrow specimens. Morphologic diagnoses were established by a clinical pathologist* without knowledge of response to chemotherapy or clinical course of the patient. An effort was made to classify all marrow specimens as either lymphocytic or myelocytic, including those 10 or 15 per cent which might be called by others "stem cell leukemia." This was not always possible on the initial specimen, but the opportunity to examine repeated aspirations permitted assignment to one or the other category. Monocytic leukemia of the "Naegeli type" was not distinguished from myelocytic leukemia. In only 4 patients was the diagnosis of monocytic leukemia of the "histiocytic type" made. These were grouped with the patients with myelocytic leukemia for analysis. Data were collected on these patients up to Jan. 15, 1960, in order to allow sufficient follow-up time for collection of complete data on survival and over-all response to therapy. By that date, 171 (96 per cent) of the patients had died.

All patients were eligible for treatment with 6-mercaptopurine, amethopterin (Methotrexate), and adrenal steroids, one or more of which were administered in accord with the treatment protocols of the Acute Leukemia Cooperative Group B.[3,4] Patients who were refractory to the above three agents were subsequently treated with other experimental chemotherapeutic agents, none of which had shown antileukemic effectiveness in the human. Supportive therapy with blood transfusion, antibiotics, and local radiation was used as indicated.

Criteria for evaluation of complete and partial remissions were those proposed by the Clinical Studies Panel of the Cancer Chemotherapy National Service Center.[5] Complete remission (C.R.) was defined as a return to normal marrow (A-1), normal peripheral blood (B-1), normal physical findings (C-1), and absence of symptoms (D-1). Partial remission (P.R.) was major improvement in all parameters (A-2, B-2, C-2, D-2, or better) not sufficient to qualify for C.R. Improvement short of remission was defined as the occurrence of a P.R. or better marrow status (A-2 or A-1), or a P.R. or better peripheral blood status (B-2 or B-1). Improvement in symptoms or in physical findings alone was classed as no response. Values for duration of survival, of remission, and of therapy were measured to the nearest month. Values less than 2 weeks in duration were expressed as 0, values of 2 weeks to 1.5 months were expressed as 1, etc. Age was dated from the time of onset of symptoms and expressed to the nearest year.

The data were analyzed by the following statistical tests: the chi square (χ^2) test,[6] the t test,[6] Fisher's exact test,[7] and the Kolmogorov-Smirnov test.[8,9] Tests of the difference between medians were made with the χ^2 test. A test for a trend in proportions, such as that for Fig. 1, was made by partitioning χ^2 according to a method described by Cochran.[10] Survival curves and remission curves were calculated using a life table method.[11] The tests of the differences between curves were made using a χ^2 test of the difference between medians and the Kolmogorov-Smirnov test. The first is sensitive only to differences between curves at the median; the second is a general test of the maximum difference between curves.

*We are indebted to George Brecher, M.D., Chief, Hematology Service, Department of Clinical Pathology, National Institutes of Health.

Two statistical tests have thus been applied to the same data and this would ordinarily increase the chance of falsely declaring that a real difference between curves exists, when there is no real difference. The procedure was adopted here of making a conclusion only when the two tests showed agreement (thus reducing the level of error below .05). For the statistical tests, the result was considered significant if the probability of the observed difference was .05 or less. For probabilities of .01 or less, the test result was considered highly significant; probabilities between .05 and .10 were classed as suggestive. To avoid the reporting of all test results, the practice was adopted in the text of using the terms significant, highly significant, and suggestive in accord with the above definitions.

RESULTS

The 178 patients with acute leukemia are classified by age at onset of symptoms and morphologic diagnosis in Fig. 1. There was a highly significant difference between the age distribution of patients with acute lymphocytic leukemia (ALL) and the age distribution of patients with acute myelocytic leukemia (AML). The proportion of patients in each 5 year age group having ALL decreases in a linear fashion for each age group up to age 20 and over. The proportions of ALL patients to the total (ALL + AML) are .95, .94, .87, .78, .32 for age groups, 0-4, 5-9, 10-14, 15-19, and 20 and over. A χ^2 test indicates significant differences among these proportions. The progressive decrease in the proportions with age is consistent with the hypothesis that the trend is linear. If the patients with AML are grouped into 10 year age groups, there is suggestive evidence that there is an excess of cases in the age groups from 30 to 70 years.

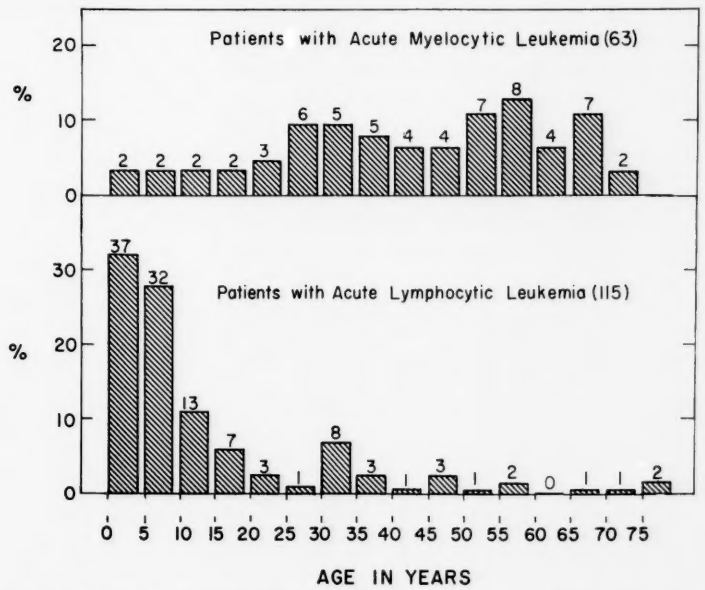

Fig. 1.—Age at onset of symptoms of 178 patients with acute leukemia (1953-1958). Patients are grouped in 5 year age groups, from 0 up to and including 4, from 5 up to and including 9, etc. The number of patients in each interval is shown over the bar. The ordinate is the per cent of the total number of patients with that morphologic type of leukemia.

A. Relationship of Age and Morphologic Type of Acute Leukemia to Response to Therapy.—For patients with ALL, the percentage showing a response for each age group is shown in Fig. 2. Many patients had 2 or more separate responses to different agents; however, only the best response to any of the agents is considered here. These data indicate that the over-all percentage of response and the extent of response vary with age. The proportion of patients achieving a complete remission becomes progressively smaller for each age group. The differences between these proportions are highly significant and are consistent with the hypothesis that the proportion of complete remissions decreases linearly by age group. The differences between the proportions of patients achieving either complete or partial remission and the differences between the proportions showing any hematologic response (complete + partial + improvements) were also highly significant by age group. However, the major contribution to the total value of χ^2 comes from the age group 20 and over, where the proportion of patients having a hematologic response was substantially less than for the age groups below 20. Although age 15 is frequently used to separate children from adults, the response of the patients aged 15-19 resembled that of the children (0-14) more closely than of the adults (20 and over). For the 15-19 age group, the proportion having any hematologic response and the proportion having a complete remission were significantly greater than for the age group 20 and over ($P = .051$ and .004, respectively, by Fisher's exact test). These proportions were not significantly different from those of the age groups under 15.

The relationship of age to hematologic response for patients with acute myelocytic leukemia (AML) is shown in Fig. 3. The percentage of patients showing a response did not differ by age groups. Responses for the entire group of patients with AML were much less frequent than for patients with ALL of ages 0-19, but were not significantly different from those for patients over 20 with ALL.

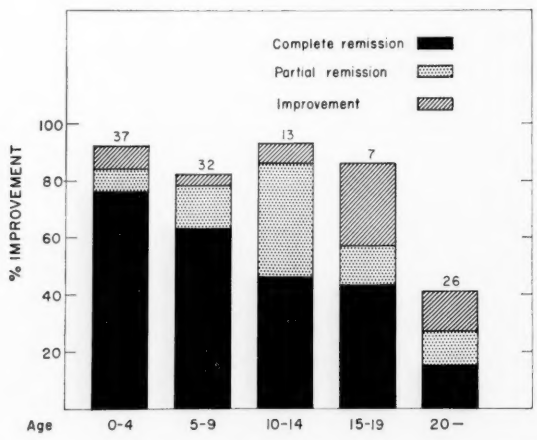

Fig. 2.—Frequency of hematologic improvement in patients with acute lymphocytic leukemia. The best response for each patient is shown. The ordinate presents the per cent of patients in that age interval. The distance from the top of each column to 100 per cent represents the per cent of patients who had no response.

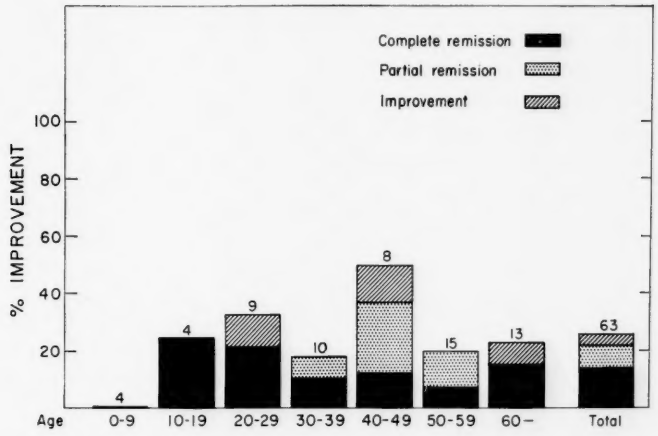

Fig. 3.—Frequency of hematologic improvement in patients with acute myelocytic leukemia.

B. Relationship of Age and Morphologic Type of Acute Leukemia to Survival.—The survival curves dated from onset of symptoms, from diagnosis, and from admission are shown in Fig. 4. In each curve, the best survival occurred in the group of patients with ALL, aged 0-19. When dated from onset of symptoms, the patients with ALL, aged 0-19, showed a significantly longer survival than the patients with ALL, aged 20 and over. The survival of patients with AML was intermediate but did not differ significantly from that of patients with ALL aged 0-19 or 20 and over. In contrast, when survival is dated from either diagnosis or admission, the patients aged 0-19 with ALL showed a significantly longer survival than patients aged 20 and over with ALL, and patients with AML. Again, survival of patients aged 20 and over with ALL did not differ significantly from that of patients with AML.

The survival from time of diagnosis for ALL patients was examined in more detail by age groups (Table I). As with response to therapy, the median survival time for the age group 15-19 was intermediate between the group 0-14 and the group 20 and over. The median for the 15-19 age group was significantly longer than for the over 20 age group but did not differ significantly from the group 0-14. There were no significant differences in median survival time among any 5 year age groups up to 20; however, there was a trend toward longer survival in

TABLE I. EFFECT OF AGE ON SURVIVAL OF PATIENTS WITH ACUTE LYMPHOCYTIC LEUKEMIA

AGE	NO. OF PATIENTS	MEDIAN SURVIVAL, DIAGNOSIS TO DEATH (MONTHS)
0–4	37	9
5–9	32	11
10–14	13	12
15–19	7	6
20	26	3

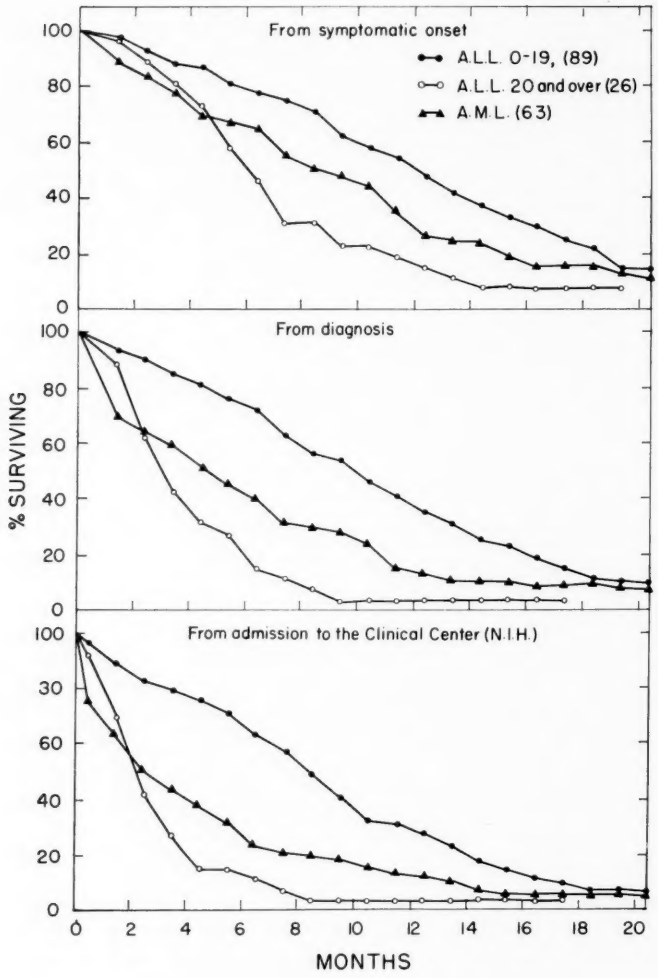

Fig. 4.—Survival of patients with acute leukemia.

the ages 5-14. This was more evident when 2 year age groups were examined (Fig. 5). A trend toward longer survival for the age groups 4-5 and 6-7 was found.

C. Effect of Hematologic Response on Survival.—The survival of patients who had shown some hematologic response to therapy (either complete or partial remission or improvement) is compared with that of patients who showed no hematologic response to therapy in Fig. 6. The patients showing a response (solid circles) evidently have a much better survival. In fact, the small fraction of patients with AML who do respond have a survival pattern similar to the large fraction of patients with ALL aged 0-19 who respond to therapy. The survival of the adult patients aged 20 and over with ALL, who respond is substantially shorter than that of the two preceding groups. The survival of the patients who

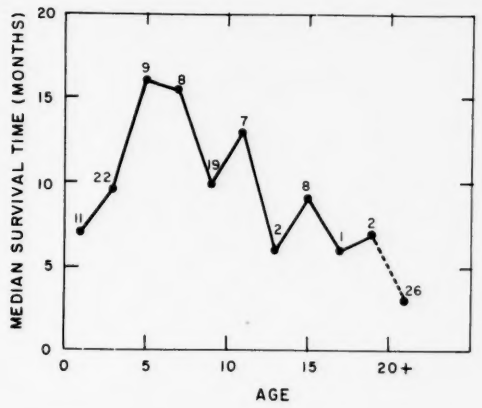

Fig. 5.—Effect of age on survival of patients with acute lymphocytic leukemia (from diagnosis). Patients were grouped in 2 year age groups, 0-1, 2-3, 4-5, etc. The plotted points are the medians for each group, and the number of patients in each group is shown above the point.

do not respond to therapy (solid triangles) is very short, for all three groups (AML, ALL 0-19, ALL over 20), and the three survival curves are similar.

The direct contribution of the hematologic response to the improvement of survival time was examined. For each patient showing hematologic response the duration of treatment with each agent which resulted in the hematologic response was subtracted from his total survival time. For many patients more than one treatment course was subtracted. The resulting data were plotted as survival curves (Fig. 6, open circles). In each of the three groups of patients the resulting curves were very similar to those for patients showing no response to therapy. These data indicate that the prolongation of survival of patients showing a response to therapy results from the duration of the courses of treatment which produced a hematologic response. There is no evidence of an additional beneficial effect on survival from having a response.

D. The Duration and Frequency of Hematologic Response.—The effect of the extent of hematologic response on its duration for all patients with ALL is shown in Fig. 7. Complete remissions had a median duration of 5 months while hematologic improvements had a median duration of only 2 months. This difference in duration was highly significant. Partial remissions were intermediate in duration, the median being 3 months. Partial remissions were significantly shorter than complete remissions, but were not significantly longer than hematologic improvements.

For patients with AML, the number of hematologic responses was small, 19. Nonetheless, the duration of the 8 complete remissions was significantly longer than the complete remissions for the patients with ALL, the median being 12 months with a range of 1 to 25 months. The median duration of the 8 partial remissions was 3 months, and of the 3 hematologic improvements, 2 months. These were not different from the values for patients with ALL.

Patients who had one episode of hematologic response (remission or improvement) frequently went on to show one or more additional episodes of hema-

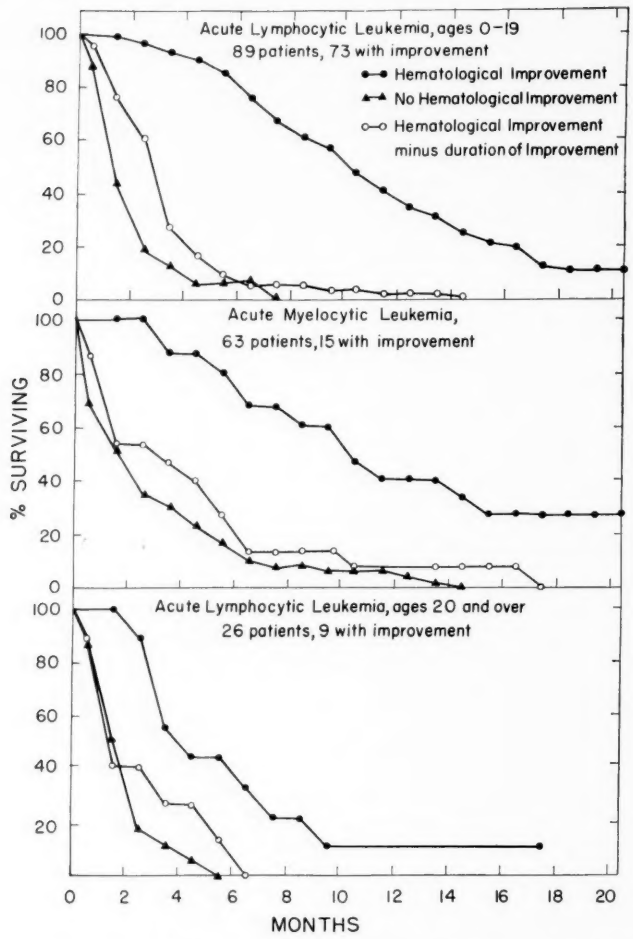

Fig. 6.—The effect of hematologic improvement on survival (from admission to the Clinical Center National Institutes of Health).

tologic response. The number of responses is given for each group of patients in Table II. The number of responses per patient showing at least one response was significantly greater for patients with ALL aged 0-19 than for patients with AML. The difference in the frequency of additional responses between patients with ALL aged 0-19 and patients with ALL aged 20 and over was not significant. However, the 6 patients with ALL aged 15-19 all had a single response and as a result the frequency of additional responses was significantly greater for the patients with ALL aged 0-14 than for patients with ALL aged 15 and over.

The response of a patient to the first course of therapy had no predictive value for his chance of response to a subsequent course of therapy (Table III). Children with ALL who failed to improve with the first drug that was used were as likely to respond to the second drug as were those who had enjoyed an excellent remission with the first drug.

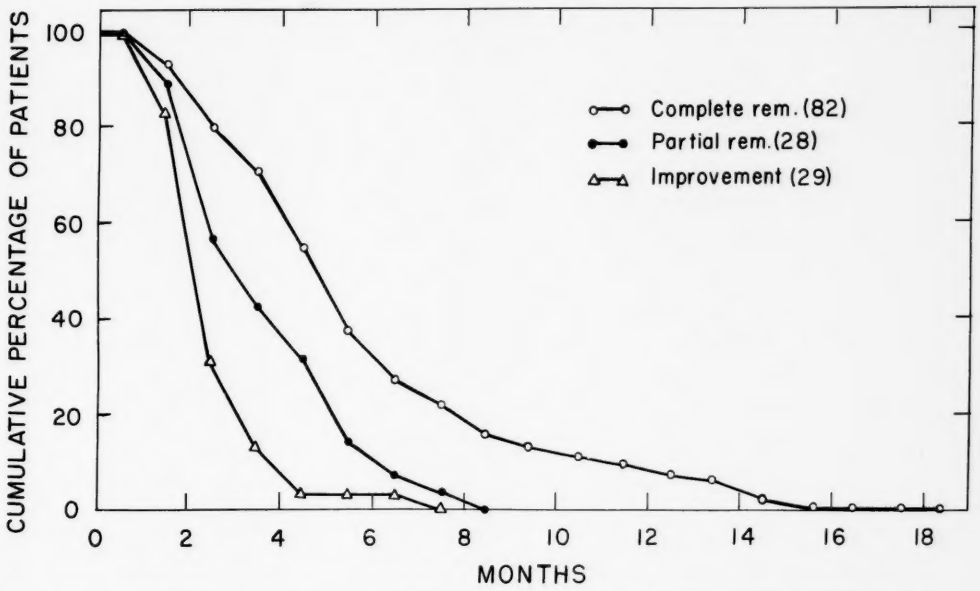

Fig. 7.—The duration of hematologic response in patients with acute lymphocytic leukemia. The ordinate shows the per cent of patients still showing improvement. The number of responses considered in each group is shown in parentheses.

TABLE II. NUMBER OF HEMATOLOGIC RESPONSES FOR THOSE PATIENTS HAVING AT LEAST ONE RESPONSE

	RESPONSES								AVERAGE
	1		2		3		4		
	NO.	%	NO.	%	NO.	%	NO.	%	
ALL 0-19	26	33	34	44	16	21	2	3	1.9
ALL 20 and over	7	64	3	27	1	9	0	0	1.5
AML	13	81	2	12	1	6	0	0	1.2

TABLE III. EFFECT OF INITIAL RESPONSE ON NUMBER OF LATER RESPONSES, PATIENTS WITH ALL (0-19)

FIRST RESPONSE	NO. OF LATER RESPONSES				AVG. NO. LATER RESPONSES
	0	1	2	3	
Complete remission	9	21	6	1	1.0
Partial remission	6	6	2	0	0.7
Improvement	3	4	1	0	0.8
No response	11	12	3	4	1.0
Total	29	43	12	5	

E. Initial White Blood Cell Count, Duration of Symptoms Prior to Diagnosis, and Presenting Symptoms.—The relationship between white cell count at the time of diagnosis and survival after diagnosis is shown in Fig. 8. For each group of patients, the median survival was longest for the patients with leukopenic levels and became progressively shorter with increasing levels of leukocyte count. There was, of course, a wide variation of survival times in each white count group. To determine the extent of the relationship between white blood count and length of survival from diagnosis, the survival time was plotted against log of the white count for the patients in the three groups. A straight line was fitted by least squares to the data in each group. The slope of the line was significantly negative in patients with ALL aged 0-19 ($P < .001$) but the negative trend was only suggestive in patients with ALL aged 20 and over, and patients with AML. Precise predictions of survival could not be made from the white blood count at diagnosis since a significant amount of variation among survival times is unexplained after the straight lines have been fit.

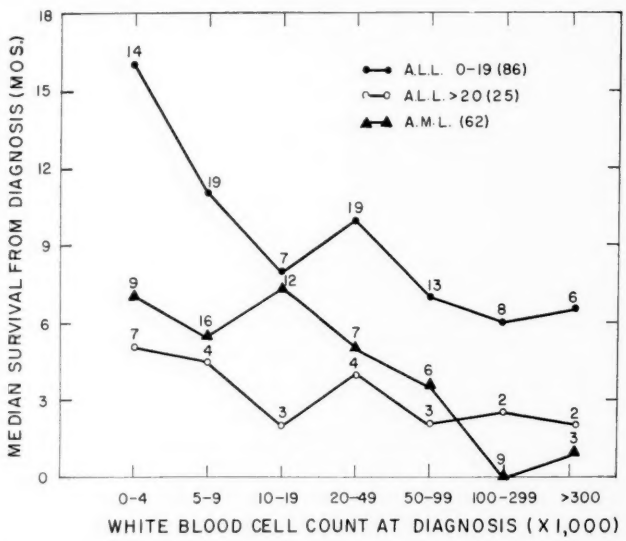

Fig. 8.—Relation between white blood cell count (per cubic millimeter) at the time of diagnosis and survival from diagnosis. The median is shown and the number of patients in each group is shown over the point.

The distribution of presenting symptoms was similar for the patients with ALL, aged 0-19, aged 20 and over, and the patients with AML (Fig. 9). However, the distribution of symptoms was significantly different for patients with ALL in age groups 0-4, 5-9, and 10-19. The young children aged 0-4 had more fever and infection and less leukemic tumor formation than the older patients, aged 10-19. There was no relation between presenting symptoms and survival in any of the groups.

The time from onset of symptoms to diagnosis is shown in Table IV. Patients with ALL aged 0-19 tended to have a shorter symptomatic period prior to diagnosis than either patients with AML or patients with ALL aged 20 and over.

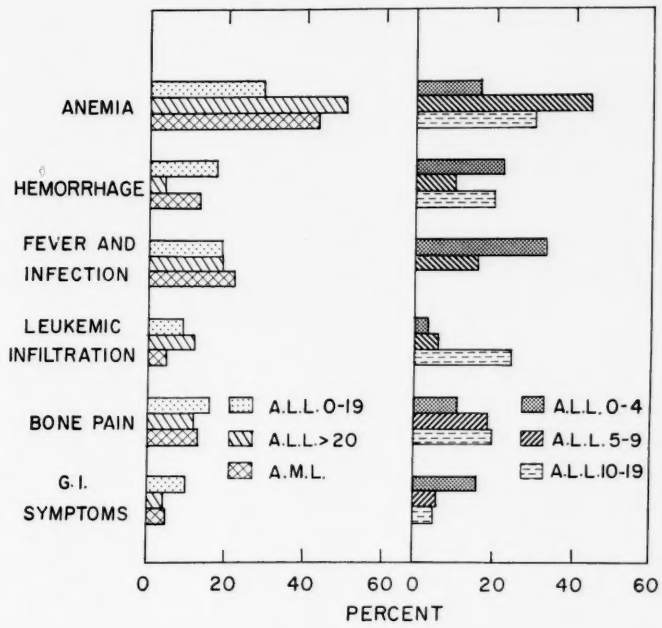

Fig. 9.—Distribution of presenting symptoms in patients with acute leukemia.

Preleukemia periods of 6 months or longer were significantly more frequent in patients with AML (22 per cent) than in patients with ALL aged 0-19 (6 per cent). There was definitely no relationship between the duration of symptoms prior to diagnosis and the duration of survival after diagnosis in any of the groups of patients studied.

TABLE IV. DURATION OF SYMPTOMS PRIOR TO DIAGNOSIS

DURATION (MONTHS)	ALL (0–19)		ALL (20 AND OVER)		AML	
	NO.	%	NO.	%	NO.	%
0	22	25	3	12	8	13
1	25	28	7	27	18	29
2	19	21	6	23	9	14
3	9	10	1	4	9	14
4	5	6	3	12	5	8
5	3	3	2	8	0	
6	1	1	0		1	2
7	2	2	1	4	6	10
8	0		0		1	2
9	0		1	4	0	
10	0		1		1	2
11	2	2	0		2	3
12+	1	1	1	4	2	3

The major immediate causes of death were hemorrhage and infection. These two major complications, alone or together, accounted for 88 per cent of the immediate causes of death, and no significant differences in frequency were found in the patient groups studied.

DISCUSSION

The clinical course of acute leukemia varies markedly according to the morphologic type of acute leukemia and the age of the patient. This is clear from an analysis of the response to chemotherapy, survival,[12,13] and the occurrence of complications such as meningeal leukemia.[14] The age of a patient with acute lymphocytic leukemia (ALL) is of great importance. The frequency of response to therapy is best in young children and becomes progressively lower with increasing age. The survival of patients with ALL under 20 is substantially longer than for patients with ALL 20 and over. In contrast, response to chemotherapy and survival do not vary with age in patients with acute myelocytic leukemia (AML). The frequency of response and survival of patients with AML is similar to that of adults (over 20) with ALL; however the average duration of the complete remissions for patients with AML is significantly longer than that for adults with ALL. As a result patients with AML who respond to therapy have a much longer survival than adults with ALL who respond to therapy. *Thus chemotherapy has underlined the importance of morphologic type and age as basic biologic factors affecting the behavior of acute leukemia in humans.*

In examining survival of the patients with acute leukemia, the point selected for the onset of the disease is of importance.[15] The use of historical back dating, that is, the use of date of onset of symptoms or date of diagnosis, results in a distortion of the true survival pattern. The deaths which occur in the interval prior to the admission to any center are omitted and the resulting curve shows falsely high values (a plateau) in its initial portion. This effect will be more marked in diseases which have relatively short survival times and thus differences in survival between groups tend to be obscured. In our group the survival of patients with AML, when dated from onset of symptoms, did not differ significantly from the survival of children (0-19) with ALL. In contrast, when dated from diagnosis or admission, patients with AML had a significantly shorter survival than did children with ALL. Moreover, when the effect of therapy on survival is studied, date of diagnosis should be preferred over date of onset of symptoms since no specific therapy is given prior to diagnosis. All three modes of dating survival, from onset of symptoms, date of diagnosis, and admission to the center have been reported in this paper to allow for comparison with both future and past studies.

The survival data indicate that the group of patients showing the best response to chemotherapy (children from 0-19 with ALL) had the best survival, whereas, prior to 1948, adults and children showed similar survival patterns.[16] This comparison suggests that chemotherapy has prolonged survival particularly in the children with ALL. However, in order to get a more direct estimate of the effect of chemotherapy on survival, the latter was analyzed separately for patients who responded hematologically to chemotherapy and for those who failed

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to respond. For this analysis, survival was dated from admission to the National Cancer Institute, since it required a precise knowledge of duration of treatment and of extent of hematologic improvement. The survival curves for the patients who did not respond to therapy were similar for the three groups of patients studied (ALL 0-19, ALL 20 and over, AML). The survival of the group of patients who failed to respond to chemotherapy was comparable to that reported prior to 1948 both as to duration and as to the fact that adults and children did not differ significantly.[16,17] In contrast, the survival of patients who had at least one episode of hematologic improvement was definitely longer, particularly for the groups ALL 0-19 and AML. Thus the improved survival time for the entire group of patients, ALL 0-19, results from the high proportion of patients who did show a response to therapy. The other patient groups (ALL 20 and over, AML), because of the relatively low proportion of patients with a response to therapy, have shown little change in their over-all survival.[18] In an effort to determine the direct contribution of hematologic improvement to the improved survival time of patients who had at least one episode of hematologic improvement, the duration of each course of therapy which resulted in hematologic improvement was subtracted from the total survival time for each patient. The remaining period of time represented the time during which the patient had active leukemia and was receiving ineffective therapy. The resulting data plotted as a survival curve were very similar to the survival data for patients who had no response to therapy. Thus the increase in survival time relative to that observed prior to 1948 can be attributed directly to the time on effective chemotherapy. The improved supportive therapy with transfusions, antibiotics, etc., has not significantly prolonged the survival of patients who fail to respond hematologically to chemotherapy. The effect of this supportive therapy may be to increase the likelihood of achieving a response to chemotherapy.

It is possible that patients with acute leukemia can be divided into those with mild disease ("responders") and those with severe disease ("nonresponders"). This might account for the differences in survival observed between patient groups. However, frequency of response to a second therapeutic agent is similar both for patients who respond and for those who fail to respond to the first therapeutic agent.[4] In addition, our data indicate that response of a patient to the initial therapy with any agent was not related to subsequent response to other agents. Thus, the frequency of subsequent response was similar for those patients who had a complete remission on first therapy and for those who had no response to initial therapy. Moreover, the survival time of the patients who fail to respond to therapy ("nonresponders") was similar to the survival from beginning of therapy for a group of patients with advanced leukemia, refractory to further chemotherapy,[19] although these latter patients had a high proportion of previous responses to therapy and would be identified as having mild disease ("responders"). Thus a patient is exposed to a high risk of death when active disease is present and this risk is sharply reduced when hematologic improvement occurs.

In a review of the literature up to 1948, Swaen[20] found only 97 instances of "spontaneous" remissions in patients with acute leukemia. In our 89 patients with ALL, aged 0-19, there were over 100 remissions. Prior to chemotherapy, the

frequency of "spontaneous" remission was less than 10 per cent[16,20,21] and two remissions occurred rarely in a single patient.[20] Of our patients with ALL, aged 0-19, more than 90 per cent had at least one episode of hematologic improvement and those having such improvement had an average of almost two improvements per patient. It is evident that chemotherapy has increased the frequency of remission. Swaen[20] reported that patients showing a remission have a longer survival than those not having a remission. This was also true in our cases and the data indicate that the prolongation of survival can be directly attributed to the duration of the various treatments resulting in remission. Thus the continued search both for new chemotherapeutic agents which can induce remission and for improved use of the presently available therapy affords the promise of more effective therapy for acute leukemia in humans.

The criteria used in this study for defining hematologic response do correlate with a beneficial effect on the course of the disease in that: (a) the duration of hematologic response correlates with duration of survival, and (b) the greater the extent of the response the longer its duration. Such objective criteria for the measurement of the frequency and extent of response to a therapeutic agent should therefore be useful in the detection of new modes of effective therapy.

The relationships between other factors and prognosis were analyzed. The level of peripheral leukocytes at time of diagnosis was related to survival, the higher the white count the shorter the survival.[22] The greatly increased frequency of fatal intracranial hemorrhage found in patients with markedly elevated white cell counts associated with blastic crisis[23] probably contributes to the poor prognosis associated with high white counts. The distribution of presenting symptoms only confirmed the protean clinical manifestations of acute leukemia and was not of prognostic or diagnostic value. The duration of symptoms prior to diagnosis was slightly longer for adults with ALL (over 20) and for patients with AML than for children with ALL (0-19). However, there was no relation between duration of symptoms prior to diagnosis and survival after diagnosis. The frequency of hemorrhage and infection as causes of death in acute leukemia emphasizes the need for better therapy of these complications.

SUMMARY

A study has been made of 178 patients with acute leukemia admitted consecutively to the Chemotherapy Service of the National Cancer Institute between Oct. 22, 1953, and Oct. 20, 1958. Response to chemotherapy and survival varied markedly according to the age of the patient and the morphologic type of leukemia. For patients with acute lymphocytic leukemia, both the frequency of hematologic response and survival were better for children (under age 20) than for adults (age 20 and over). For patients with acute myelocytic leukemia, the frequency and extent of response did not vary with age. The response and survival for these patients with myelocytic leukemia was similar to that of adults with lymphocytic leukemia. However, for patients having a complete remission, the median duration of the remissions was significantly longer for patients with myelocytic leukemia, than for adults with lymphocytic leukemia. The survival time for patients who had a response was substantially longer than that for pa-

tients who did not. However, if the total time each patient received chemotherapy which resulted in a response was subtracted from the survival time, the resulting survival curves were similar to those for patients who failed to respond to therapy, and similar to the survival pattern reported prior to 1948. Thus the risk of death during periods of active disease has not changed during the past 10 years and the improved survival can be attributed directly to the duration of the hematologic responses resulting from chemotherapy. The duration of hematologic response was directly related to the extent of the response. The response to subsequent courses of therapy was found to be independent of response to the first course of therapy. There was a trend toward shorter survival the higher the white count at the time of diagnosis, but there was no relation between presenting symptoms or time from symptoms to diagnosis and survival. These data document the alterations in the natural history of acute leukemia resulting from currently available chemotherapy and can be useful for comparison with data accumulated in the future when newer forms of therapy are available.

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Vol.
19

ol. 14
1961

RECORDING SYMPTOM AND BEHAVIOR OBSERVATIONS ON A METABOLIC UNIT

ROBERT M. BEAUREGARD, M.S.W., RALPH W. WADESON, JR., M.D., AND LOUISE WALSH, R.N.

BETHESDA, MD.

From the Social Service Department, The Clinical Center, the Adult Psychiatry Branch, Clinical Investigations, and the Metabolic Unit, The Clinical Center, National Institutes of Health

(Received for publication March 28, 1961)

THE influence of emotions and behavior on body physiology during the course of a metabolic balance study has not been fully evaluated. Frequently, clinical staff members express a desire to keep patients on an "even keel, happy and satisfied, and without complaint" just in case variations in these factors are significant. This approach, however, may overlook underlying feelings of anger, depression, tension, or other significant emotions. These may be hidden by the patient to some extent though somehow "felt" by members of the staff. Opinion varies from considering such factors insignificant to the other extreme of indicating they must undoubtedly affect metabolism, and metabolic data are of questionable value unless these variables are taken into account. Few attempts have been made to evaluate this issue.

A first step in analyzing the influence of one variable on another is to develop a means of measuring the factors involved. Instruments are available to collect and quantify some physiologic data. This paper describes an initial attempt to develop a simple, consistent, continuous, and standardized instrument for recording nursing observations of symptoms and behavior. Comparison with physiologic data will be the subject of another paper.

DEVELOPMENT OF THE INSTRUMENT

The development of a base-line instrument for recording observations of symptoms and behavior entailed several stages and a few missteps. Actually, the recognition that such an instrument was necessary prior to comparing significant psychological data with data on physical illness, metabolism, and other facets of the patient and his environment was a major step. The literature provided several ultimate study areas but little initial direction.[1-14]

The investigators turned to the clinical staff and records for leads. At the outset, shortcomings in observing and recording became apparent. There was a paucity of information regarding incidents and situations in the nurses' and doctors' progress notes. Example No. 1 shows the dearth of observational data, and the inclusion of a narrative description by the social worker gives some indication of the difficulty in quantitative interpretation.

Several charts of patients on a metabolic study unit were observed to show great variation and contained the kind of observations of behavior and symptoms that appeared useful. Not only did recorders vary from shift to shift, but the same recorder showed great variation, depending upon such factors as work load, time for recording before going off duty, mood, immediate recall, and reactions to a particular patient. It was not unusual to find several days, and at times weeks, when only physical and metabolic observations were recorded with no mention of variations in behavior and symptoms indicated. An example of this pattern is displayed below.

7/24	6:15 A.M.	Metabolic fluid total 1,309 ml., dist. H_2O 800 ml.
	6:15 A.M.	Twenty-four hour urine total 1,732 ml., dist. H_2O 230 ml. 6:15 A.M. 7/24/59 to 6:15 A.M. 7/25/59
7/24	9:35 A.M.	Large amount of soft light brown stool with carmine
	9:00 P.M.	Metabolic nourishment consumed
7/25	6:15 A.M.	Metabolic fluid total 1,310 ml., dist. H_2O 1,071 ml.
	6:15 A.M.	Twenty-four hour urine total 1,941 ml., dist. H_2O 210 ml.

This kind of report continues until Aug. 6, 1959, where the following notation is made:

8/6	6:15 A.M.	Metabolic fluid total 1,310 ml., dist. H_2O 762 ml.
	6:15 A.M.	Twenty-four hour urine total 1,609 ml., dist. H_2O 237 ml. 6:15 A.M. 8/6/59 to 6:15 A.M. 8/7/59
	8:45 A.M.	Complains of rapid irregular pounding heartbeat. States she has fluttering sensations from neck to abdomen. Attributes phenomenon to eating, then lying still. States she has had these attacks for approximately one month.
	1:55 P.M.	Was standing outside her room door and asked if the doctor had left the floor, said, "For the last couple of days I have felt sort of keyed up. My heart has been acting up." When asked how, said, "Fluttering like. Don't call the doctor. It may not be that important."

For purposes of the metabolic study the nurses are required to record volumes of emesis, suction material, stool, menstruation, food, fluids, and urine. In their training for these studies, it is recognized that observation is one of the most important and helpful aspects of clinical research. "It is important to describe the behavior of the patients, since his actions may have both physical and emotional significance."[15] However, with the pressure of the usual routines, very little time or energy remains to write full descriptions of symptoms and behavior. Certainly, the time required for writing the behavior observation shown above is greater than for writing the required comments about urine, stool, etc.

What could we use to obtain this needed information in a simple, meaningful, and consistent way with minimal effort? In addition, we would want to translate this into a presentation over a period of time, to compare patients and other data,

EXAMPLE NO. 1. MRS. W., A 57-YEAR-OLD WOMAN WITH OSTEOMALACIA. RECORDING IS OVER A 3 WEEK PERIOD

SOCIAL WORKER	DOCTOR*	NURSE*
4/22. Patient Interview.—Reacting to several pressures today—continued hospitalization, loss of roommate, husband adjustment to home in that husband recently discharged from TB sanitarium. Patient looked irritated and angry. When I verbalized recognizing these feelings, patient admitted she was irritated with treatment here in that no one gives patients credit for their ability to think, act, make up their own minds. She specified in terms of amount of exercise she can do contrasted with doctors' requests, social mixing, and other staff "suggestions." Patient said, "I know what they have been hinting at all along." As I said I had been a part of this hinting, patient appeared to relax and describe how she had always been withdrawn, not needing as much mixing, that she could get along and was upset by the "pushing."		
4/29. Medical Rounds.—Doctor reported patient more cheerful since she was told her discharge date was around end of May.		*4/25, 12:00 noon*: Patient came walking down the hall to get her medicine. She appears to be increasing her activity without encouragement. *10:00* P.M.: Patient voided in another patient's urinal. Urine put in separate collection bottle from 24 hour collection.
5/1. Patient Interview.—Patient said she was relieved at being told discharge date even though it is to be a longer stay than anticipated. Patient seemed to need to talk over many things with some reflection to the past, especially the last 1½ years. This mainly related to the family adjustment to her husband's return from the TB sanitarium. Patient is aware she wants to be home now to take charge of husband's adjustment rather than commanding at a distance via the telephone. I explained the naturalness of this process as a means of reassurance and recognition of the pressure she was experiencing. She described a letter from the TB sanitarium regarding her husband's condition and how she at first did not want to show it to her husband. I related this to her desire to be home to take care of him and yet not being able to. I mentioned that he was probably familiar with his disease, having been in the sanitarium for a long time. This moved us into her description of the uneasiness of being dependent on their two married children and how this has been brought on by illness and medical expense.	*4/30.* States today that for past several nights has been awakened several times with "heavy feeling" in lower abdomen and has to void.	*4/30, 2:00* P.M.: Has been most outgoing this afternoon, visited with other patients and was talkative with the nurses. Appears cheerful and happy.
5/6. Medical Rounds.—Patient experiencing a "heavy feeling," lower abdominal pain. Doctor says this characteristic of osteomalacia yet he cannot rule out cancer. Social Worker indicated that patient concerned about her granddaughter's positive TB checks. Doctor suggested that he might call the public health facility doing the checks regarding the granddaughter and in this way assist the family in their adjustment to husband's TB.		*5/3, 7:30* A.M.: Complains of sharp "pain in left eyeball" which she gets when opening her eyes too quickly and the light striking. States she has not reported this to the doctor because every time he visits she has a list of complaints and hasn't had enough courage. States she is curious as to the cause. *10:30* P.M.: Patient complained of being "sick at stomach" while at chapel. She was returned to unit.
5/8. Patient Interview.—Patient generally feeling better, more active on the unit in terms of exercise and relating more to other patients. She admitted more apprehension regarding home adjustment of her husband and her need to get away from thinking about it, thus increasing activity. She has often been seen by staff members with other patients on the unit, in the solarium, or in other rooms this week. She is also requiring more pain medication, complaining of pain in the back and neck muscles.		

*Only symptom and behavior notes included. Other data such as intake-output record, medications, not included here.

such as metabolic calcium balance information displayed in much the same manner.

In summary, our impressions were obtained from conferences, medical records, and informal discussions. Our approach became: (1) to examine medical records of patients on the metabolic study unit and extract from the nursing notes all the descriptive comments, words, and ideas pertaining to behavior and symptoms; (2) to evolve a list of general symptom and behavior items that some of the material obtained from the chart could be subsumed under. Initially suggested were such dimensions as distress, depression, retardation, agitation, crying, inability to cry, anxiety, nervousness, muscle tenseness, irritability, sociability, withdrawal, intake and output difficulties, anger expressed, weakness, fatigue, and complaints regarding symptoms; (3) to arrange this collection of descriptive information from the medical records and suggested items along psychological, psychophysiologic, and physiologic lines; (4) to discuss this organization with the clinical staff.

Following this basic outline, one patient's record was charted over a 6 month period of hospitalization (Fig. 1). The method of recording was graphic. The crude clusters of behavior were not greatly significant but there were a few interesting results. There are two things of special interest in Fig. 1. First, the periods just after admission on August 5 and after returning from pass October 25 and December 30 portray a pattern of adjusting to or settling down to hospital routine. After admission the patient was observed as having good days and stressful days. At times she was distressed, depressed, crying, sleepless, and at times in a good mood or better. On October 25 she returned from a one week pass and for 3 days was observed at varying times as being distressed, depressed, weak, and in a good mood. She returned from her next pass after the Christmas holiday on December 30, and was immediately placed on formal study, i.e., diet and collections. She spoke of some pain but managed without other significant complaints until January 5, when another cluster began running through January 17. One wonders if the complaints would have been expressed initially if a few days of adjustment had been allowed prior to the beginning of the study as had been the case previously.

Second, the most striking thing in Fig. 1 is the absence of observations during the periods of the metabolic study. From the routine records, there are not sufficient observations to make comparisons with laboratory data. The "no notes" line was used to indicate the absence of observational data. Whenever a 24 hour period contained intake-output and occasional pass information but no more, a mark was placed in this row. Of 204 hospital days, 137 days showed no record of symptoms or behavior. It is possible that the patient was displaying her "usual" pattern, whatever that may have been. However, the need for some means of recording this information to establish a pattern and understand variations from it became apparent. Thus, the nurses depicted a pattern of adjustment to hospitalization which is often fraught with distress,[16] but a means of obtaining continuous and consistent observations was needed.

The means became a form (Fig. 2) incorporating the organization of symptoms and behavior items contained in Fig. 1. The combination of check list and

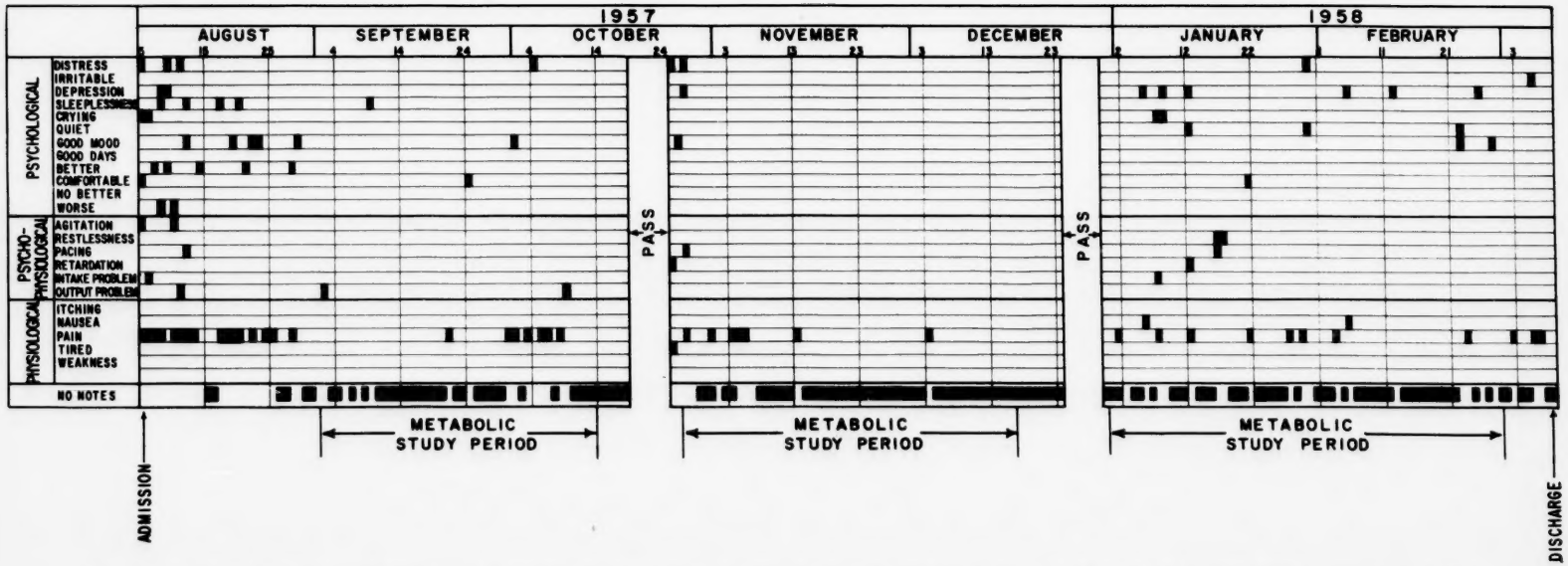

Fig. 1.—Psychological, psychophysiologic, and physiologic comments from nurses' progress notes on Mrs. K., a 64-year-old woman with osteoporosis, during her hospitalization period, Aug. 5, 1957, to March 8, 1958.

SYMPTOM AND BEHAVIOR OBSERVATIONS

Name of Patient Mrs. K. Rater & Shift Smith 4-12 30 p.m. Date 7/16/59

	none	minimum	minimum to moderate	moderate	moderate to maximum	maximum	REMARKS
DISTRESS-overall discomfort from any cause			✓				
DEPRESSION-unhappy, blue, hopeless, subdued, moody		✓					
RETARDATION-slowing down of physical and mental activities		✓					
AGITATION-restlessness, wringing hands, shaky				✓			concerned over BMR in A.M. Reassured
CRYING	✓						
INABILITY TO CRY-expression of wish to cry but cannot		✓					
ANXIETY-nervous, jittery, tenseness				✓			very anxious to carry out procedures properly
ANGER EXPRESSED-irritability, peeved, touchy		✓					
WITHDRAWAL-isolation from staff and patients, no socializing		✓					
COMPLAINTS ABOUT:							
PAIN			✓				
WEAKNESS-fatigue			✓				
EATING DIFFICULTY							
Nausea		✓					
Swallowing		✓					
Other	✓						
DIGESTION DIFFICULTY							
Heartburn	✓						
Indigestion	✓						
Gas	✓						
Other	✓						
EXCRETION DIFFICULTY							
Constipation	✓						
Diarrhea	✓						
Urination		✓					on aliquots
Other	✓						
RELATES TO OTHER PATIENTS					✓		visiting in patients' rooms, cheerful
DEGREE OF IMPROVEMENT EXPRESSED SPONTANEOUSLY BY PATIENT		✓					

Instructions: A mark should be placed in the appropriate column for each descriptive term. Any amount of the symptoms and behaviors observed is important to record on the scale, even if it is expressed or observed for a short time during the shift. If no observation of a particular descriptive factor is made during a shift, mark the 'none' column.

Fig. 2.—Form used initially by nurses to record symptoms and behavior of patients.

remarks was used in order to obtain the valuable contributions these observers could offer, yet not overburden them with a need to write long descriptive and time-consuming observations.

PILOT PROCEDURE, STUDY SETTING, AND DEFINITIONS

Two trial periods were used to test the instrument, the first observing 3 patients for 2 weeks, June 18 to July 2, 1959 (Fig. 3), and the second observing 2 patients for approximately 2 months, one from July 15 to Sept. 10, 1959, and the other July 6 to Sept. 5, 1959 (Fig. 4).

The mechanics of running the trial periods were simple. The raters were

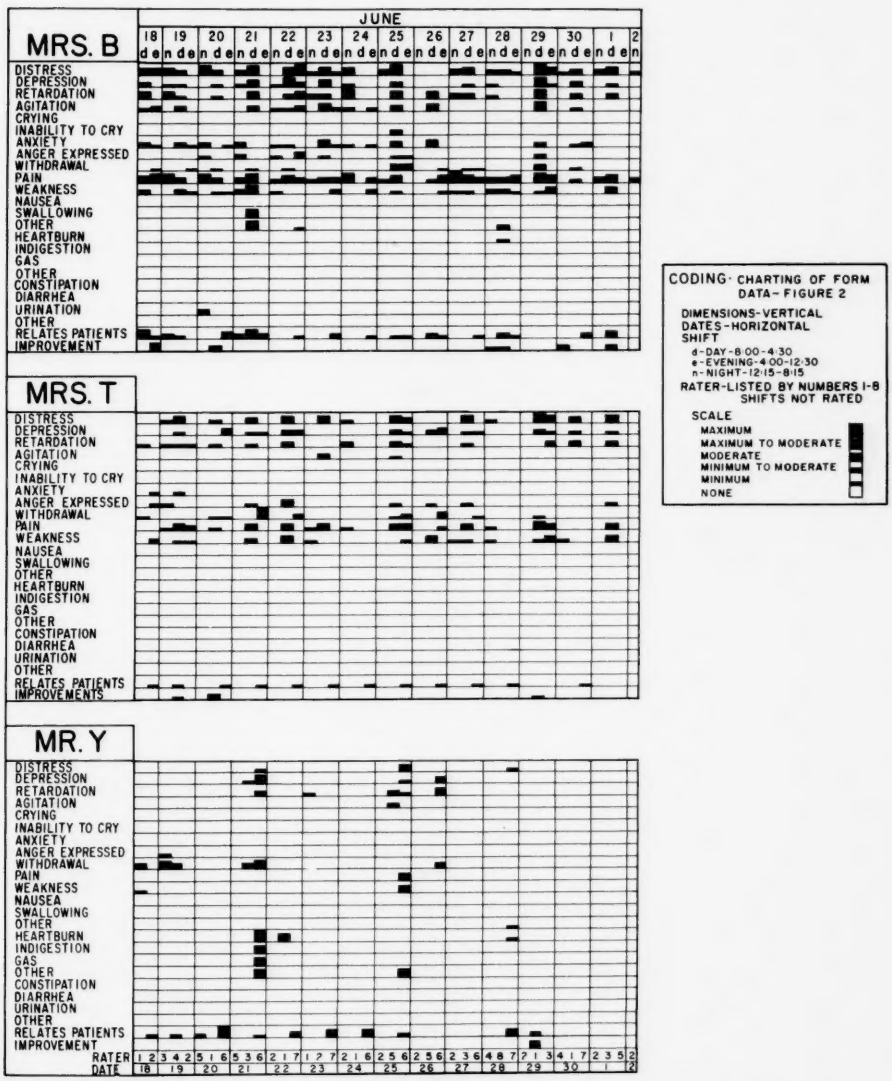

Fig. 3.—First trial period. Symptom and behavior observations, June 18 to July 2, 1959, on Mrs. B., a 62-year-old woman with osteoporosis and rheumatoid arthritis, Mrs. T., a 70-year-old woman with osteoporosis, and Mr. Y., an 18-year-old man with osteoporosis.

briefed by the head nurse who also supervised the collection process. Observations were recorded on the form (Fig. 2) during each nursing shift by the nursing team shift leader. The form was completed toward the end of a shift. Some team leaders drew on the observations of other team members and some limited the record to their own observations. The form was then enclosed in an envelope and turned in to the head nurse. She turned them over to the social worker who translated the observations onto a graphic record depicting all the data over time, Figs. 3 and 4. The remarks were not depicted on the graph but were used to qualify and clarify the data.

The hospital setting from which the sample was drawn is a nursing unit of 22 beds in the Clinical Center* of the National Institutes of Health. The particular study population consists of patients whose mineral metabolism is being studied, who occupy a maximum of eight beds on the unit.† The usual diagnoses are osteomalacia, osteoporosis, Paget's disease, and other bone conditions.

The controlled climate of the metabolic study unit and the observed high degree of stress experienced by these patients prompted their use as a sample. Symptom and behavioral changes take place in every medical study environment. The more pronounced control and degree of change on this nursing unit might help delineate the form items.

The mineral metabolism study varies levels of calcium intake while other conditions are held as constant as possible. The diet is constant from day to day and dictated by the project with emphasis on a specific mineral intake of varying levels.[17] The patient has an individually prepared and measured meal, his own pitcher of distilled water, and his own stool can and urinal. Constant, repetitive sameness directed toward accurate measurement of intake and output is the goal of the well-executed metabolic balance study which may extend over a period of 6 weeks to more than a year.

Before the findings of this study are presented, some definitions of terms should be set out:

1. The unit of observation depicted on Form 2 and referred to in the text is an 8 hour nursing shift, generally referred to as day, 8:00-4:30; evening, 4:00-12:30; and night, 12:15-8:15.

2. Symptom and behavior observations on Form 2 represent a composite record by item and remarks of the impressions of the recorder during an 8 hour nursing shift. The rater was free to draw on direct observation of patients and observations reported to the rater by other staff members of that shift. The actual recording was the responsibility of the rater.

3. Items refer to the 24 factors used in the left hand column (distress, depression) of Form 2 (Fig. 2) to standardize the observations of symptoms and behavior.

4. The rater was the individual responsible for doing the actual recording on Form 2.

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*The Clinical Center is the 500 bed research hospital of the United States Public Health Service opened in 1953, to house patients being studied by the National Institutes of Health.

†Dr. G. Donald Whedon, Assistant Director of the National Institute of Arthritis and Metabolic Diseases and Chief of the Metabolic Diseases Branch, and Dr. Leo Lutwak, Senior Investigator of the Metabolic Diseases Branch, encouraged and offered valuable consultation for this project.

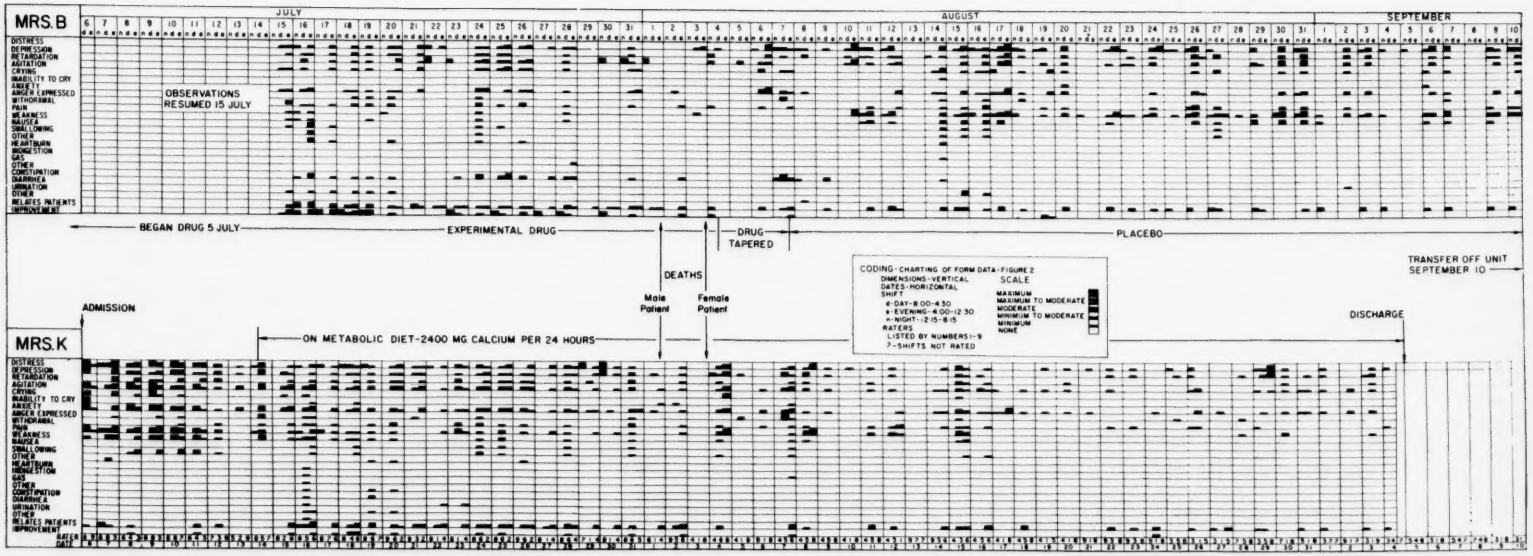

Fig. 4.—Second trial period. Symptom and behavior observations of Mrs. B., a 62-year-old woman with osteoporosis and rheumatoid arthritis, July 15 to Sept. 10, 1959, and Mrs. K., a 64-year-old woman with osteoporosis, July 6 to Sept. 5, 1959.

5. Scale referred to the response choices tested as none, minimum, minimum to moderate, moderate, moderate to maximum, and maximum on Form 2. This was an attempt to add an intensity factor to the items. Although some of the items have mensurative possibilities, we recognize that, at this stage of instrument development, the continuum is not clear and is at best a crude scale.

FINDINGS

The evaluation of the findings involves a comparison of the observational data with other material and knowledge available that depicted similar information. At this stage, laboratory data were not ready for comparison.*

Continuous Observations.—What did we learn about the patients from the data? Shift by shift observations were obtained on the 3 patients utilized during the 2 week period, and shift by shift observations on the 2 patients over the 2 month period. Of a total of 479 possible observations, 451 were completed. The missing 28 reports were due to an observer's forgetting to fill out the form, or loss of the form in the collection process. This means that, during the course of the two trial periods, 94 per cent of the shift observations were recorded and turned in. This provides a picture of observations on a continuous basis.

Comparison With Other Methods of Observation.—Certain advantages and disadvantages can be demonstrated by comparing the information obtained from the form observations with other methods of observation. Example No. 2 presents a cross-section of observations—social worker's impressions, the doctors' and nurses' notes, and the form observations—over the same time period. Pain is noted throughout the observations from the four sources. Some reduction in intensity of pain is noted on the form, whereas there is no apparent attempt in the other records to describe change in this factor. The sparcity of information in the progress notes and the difficulty of eliciting such measurements from the social worker's narrative are apparent as they were in Example No. 1. There are other changes in the picture of the patient's condition noted on the form.† The discrepancies among observations, such as depression, may be due to form inadequacies as well as other differences such as rater variability.

Situation Analysis.—Data were evaluated by comparing recorded symptom and behavior observations with situations where behavior changes were expected: (1) a change in personal physician; (2) 2 deaths on the unit; (3) change in medication; (4) adjustment period following admission; (5) beginning and ending of metabolic study.

Situation 1.—A change in ward physicians took place between June 17 and July 7. In the interim, the chief of the study branch assumed medical care responsibilities. Mrs. T., who had been hospitalized for 8 months, appeared to

*Analysis of the laboratory data has been taking one to two years after the collection period. This precluded its use in this paper and is another indication of the importance of having quantitative behavioral records that can be meaningfully referred to at a later date.

†Some picture of change might be obtained from the recording methods presently employed in medical charts if a record were made when a change from the "routine" or "usual" pattern was observed. This would require some consensus on "routine" or "usual." At times, a patient is recognized as usually pleasant, overactive, withdrawn, or hard to get along with. However, a norm type record and a consistent record of unusual observations are not maintained.

EXAMPLE NO. 2. MRS. T., A 69-YEAR-OLD WOMAN WITH OSTEOPOROSIS. CROSS SECTION OF OBSERVATIONS, JUNE 29 TO JULY 2, 1959

SOCIAL WORKER	DOCTOR	NURSE
7/1. *Patient Interview.*—Mrs. T.'s doctor of more than a year recently left the hospital for a one-year assignment elsewhere. Patient commented occasionally re his going but had not expressed any negative feelings until today. She at first wondered if he was settled on the new job. I asked if she felt settled. She said I knew she did not like changes and although she knew some of these changes were necessary (change of doctors), it did not mean she had to like it. "I'm always stuck." This was followed by patient commenting on the plan to have her go out for 2 or 3 weeks in August. She said she hoped she would not have to stay out more than 2 weeks. There were so many things for her to do at home and so many plans to make in order to go there. Besides considering all these things, her hip had been giving her considerable pain the last few days. I commented that she probably felt like taking off too but just did not feel up to it. She said, "I told Dr. W., 'Doctor, you know I'm awfully tired,' and he made light of it." I replied that her hip and this whole business tired and aggravated her. "My hip kind of aggravated me—must be those metal screws in my hip or thigh. I used to think my left side was my good side. I'll bet Dr. L. (doctor who left) got many a laugh out of that." I commented on the difficulty of getting used to another doctor, the sense of being stuck and uncertain, and assured her that there was no intention of making light of her condition and that her care was a serious matter. I felt she was verbalizing her dependency on this setting and her previous doctor in particular. It seemed important to help her express her uncomfortableness, allow her some area for ventilation, yet consider these matters seriously in order to provide sufficient support through a difficult transition period. *Rounds.*—Patient appearing more withdrawn. Hip bothering her. Will consider 2 week period out of hospital in August, depending on patient's condition at the time.	6/29. Still some aching of right ileum and lower back.	6/30. Mrs. T. appears to be fatigued; she seems less enthusiastic about her physical condition. 7/2. Seems very depressed because her cousin told her that she wouldn't be able to take her the couple of weeks she will be out of the hospital.

FORM*

	JUNE		JULY	
	29	30	1	2
	d e	n d e	n d e	n d
Distress	X x	x	X	
Depress	X x	x	x	
Retardation	X	X	X	
Agitation				
Crying				
Inability to cry				
Anxiety				
Anger expressed			x	
Withdrawal	x			
Pain	X X		X	
Weakness	x X	x	X	
Nausea				
Swallowing				
Other				
Heartburn				
Indigestion				
Gas				
Other				
Constipation				
Diarrhea				
Urination				
Other				
Relates patient		x		
Improvement				

In addition to the above quantitative measures, the remarks qualified the measures as follows: On 6/29, pain was described as "bone pain" and patient was tired because of pain. Withdrawal conditioned by remark that she has no roommate. Reluctance to socialize explained as patient quoted as saying some of patients "are a bunch of old crocks; they have every misery known."

*X denotes maximum degree and x denotes moderate degree.

enjoy a passive dependent relationship to her doctor, and had frequently expressed appreciation for the highly organized unit routine. The staff felt this transition period was difficult for her. Fig. 3 and Example No. 2 portray Mrs. T.'s increased distress and pain during the latter part of June. This is not clear cause and effect evidence, but she had been observed to withdraw and evidenced more difficulty during this period than prior to the announcement of the doctor's departure.

Her initial relationship to the new doctor was almost euphoric before she "settled down." It would have been useful to record that period on the form also. Indeed, the value of continuous measurements over the entire period of this woman's hospitalization is evident here. As it is, we are limited to a 2 week period that portrays a woman in distress, depressed, in considerable pain, weak, angry, and withdrawn. We have to depend on recall to realize that the intensity of these expressions was other than her usual pattern. Few overt references to the change were made. However, the patient was noted in the remarks section of the form on June 23 to be feeling somewhat better and was quoted as saying she knew Dr. W. sustained interest in the patients and "after all, he taught Dr. L." (doctor who departed).

The second patient, Mrs. B., was transferred from a different unit to the study in late May and hardly knew the departing physician, Dr. L. Her behavior continued as it had apparently been on the previous unit, according to nursing reports. No particular response to Dr. L.'s leaving was evidenced by her.

The third patient was Mr. Y., an 18-year-old male, who had identified strongly with Dr. L. during a previous hospitalization. He was admitted just prior to Dr. L.'s departure. No direct reference was spontaneously offered by the patient regarding this change. The social worker discussed it with him, but on the unit he continued to be quiet and withdrawn. Interestingly enough, the form record failed to offer much evidence from the observers. The remarks described his wish to be discharged and his reluctance to complain because he was "afraid you'll put it on the report and I might have to stay longer." He spent much time at the metabolic chamber whenever possible. This was where the patient and Dr. L. had spent time discussing the patient's potential scientific skill.

Situation 2.—The second situation involved the deaths of 2 patients on the unit. The first, a man not well known by our 2 patients, died at 8:00 P.M. on Aug. 1, 1959. The second, a woman, died at 11:00 P.M. on Aug. 3, 1959. She had been a roommate of Mrs. B until Mrs. B. had requested to be moved on June 23, 1959. Mrs. B.'s and Mrs. K.'s responses are described.

Mrs. B. was recorded as displaying minimum anxiety and withdrawal after the first death, but no qualifying comments were noted in the remarks or progress notes. The absence of her usual pattern of relating to other patients and expressing improvement tended to confirm her withdrawal and reaction. However, her response to the second death was more definitive. She was observed on two shifts as being distressed during the day and evening when it was known that her former roommate's condition was getting worse. The night shift observed her as depressed and retarded, with the remark that she was "upset due to death of another

patient on the unit—came out to be weighed at 6:15 A.M. with pajamas and robe on"; this is not the specified attire for weighing. The first 2 week trial period, Fig. 3, reflected the difficulty Mrs. B. was having while rooming with the moribund patient and the recorded remarks include, "concern over her roommate's confusion," "complaints of personal habits of roommate," "just can't stand to stay in room another night." It was an unpleasant experience but difficult for her to request the move because rooms are for 2 patients and compatibility is highly valued on the unit. She must have been especially threatened by the condition of her former roommate who became increasingly confused and disoriented, and finally died. During the ex-roommate's steady decline, Mrs. B. occasionally mentioned her own forgetfulness and confusion and was frequently reminded of it by her husband. The significance of Mrs. B.'s response was again evidenced on August 10 (Fig. 4) when another roommate was moved by administrative decision. Mrs. B. was rated as in minimum distress, depression, and retardation. The remarks describe her as "slightly depressed over roommate moving to another room but reassured after explanation." Toward the latter part of her tenure on the metabolic unit she was able to discuss her fear of "losing my mind."

Mrs. K. had been known to dwell on depressive experiences and react to them in her surroundings. Her record (Fig. 4) appeared to reflect a response to both deaths. These are somewhat delayed responses, but a pattern seemed to appear. On the evening of August 1, when the first death occurred, Mrs. K. was observed as somewhat agitated and unable to cry. The next day she was unable to cry and by the evening of August 2 she was recorded as minimally distressed, depressed, retarded, agitated, anxious, withdrawn, in pain, yet relating to patients and expressing some sense of improvement. Whatever all these ratings mean, there appeared a change in her previously observed behavior. The second death was followed by a similar though more intense response pattern. In addition, a remark written on the August 4 night shift said, "seemed upset due to death of another patient on the unit." Also, on August 5, a change in her usual routine of doing things was noted.

Situation 3.—The third situation involved changes in medication from placebo to drug to placebo without the patient being informed of these changes. This is the most dramatic situation portrayed on the form. The Chief of the Metabolic Diseases Branch suggested a second period of recorded observation because of the clinical change after initiation of the drug.

During the first trial period (Fig. 3), June 18 through July 2, Mrs. B. was on placebo and her symptoms as reported prior to admission and as observed by the staff after admission were multiple. Pain, distress, and retardation were intense and occupied much of her conversation with other patients. On July 5, the experimental drug was initiated and by July 15, when the observations were again initiated, a strikingly different picture was evident (Fig. 4). Pain had become practically nonexistent and other complaints were markedly reduced. She was still relating to other patients, but the content of her discussions revolved around how much improvement she felt. Her recorded anxiety level was not greatly changed, but her anxiety possibly related to the sudden improvement and fear it would not last. Tapering of the drug began on August 4 and the last

was given on August 7, at which time the drug capsules were replaced with placebos. Her remarks indicated that she wondered if there had been a change. She expressed increasing distress, feeling of being let down, retarded behavior, and anxiety. On August 10, she was described as having high distress, pain, and retardation. And she also had "chest pain and a fluttering feeling." Many of the symptoms observed before administration of the drug returned, although it took the patient more than a week to realize the drug had probably been discontinued. The lower intensity of her complaints after discontinuance of the drug, as compared with those in the period before, might have been due to several factors—the drug's unknown residual effect, her awareness that something could be done for her condition, her more secure adjustment on the unit, the knowledge that the completion of her study was near at hand, and expectation of relief after the study requirements were completed. It was of interest that on September 6 she was recorded as saying she felt awful—"these old pains of mine, ever since Dr. W. said he changed my medicine I've had them." She was not told this by Dr. W. until just prior to discharge, some 2 to 3 weeks after the drug had been discontinued. However, the recorded observations indicated an intensification of physical complaints and reduction in expressed improvement soon after the drug was replaced by placebo.

Situation 4.—The fourth situation of the admission adjustment period was displayed in Mrs. K.'s record (Fig. 4). She has been hospitalized several times for study during the past few years. Her condition was usually poor on admission and, after a somewhat difficult period, it leveled off to a mild amount of complaining that seemed normal for her. The complaints become more intense with minimum external stimulation. The record showed fairly consistent high day and evening measurements through July 14, when the reduction was noted. It is interesting to compare this admission to her previous hospitalization which was used in developing the form and is represented by clusters of behavior in Fig. 1.

Situation 5.—Also portrayed in Fig. 4 is the fact that Mrs. K. completed the preparatory work-up and officially started the metabolic routine on July 14. It has been the experience of the staff that there is a sense of accomplishment and relief when the study gets underway. No particular contrast can be noticed at the end of Mrs. K.'s study. The increased distress and depression on August 29 were qualified in the remarks as relating to not feeling well because of a broken tooth. It may be more significant but is not as clear.

These situations demonstrated that the data obtained on our form register a graphic portrayal of symptom and behavior observations. Some patterns were obvious over a period of time, and a few situations took on meaning (deaths on the unit) when compared with the recordings of the before and after periods. Although there was value to this method of eliciting and recording observations, it needed revision prior to further investigation via such a recording instrument.

REVISED FORM

Formulation of the revised form was based on use of the form (Fig. 2) during two trial periods, on raters' comments, and on decision of the investigators.

Figs. 3 and 4 depict the use of the form. As previously indicated, 94 per cent of the shift observations were recorded and reported. Table I organizes the data as to the rater's use of items. Generally, distress, depression, retardation, agitation, anxiety, pain, and "relates to patients" were utilized most, while crying, inability to cry, and gastrointestinal complaints were used least.

TABLE I. RATER'S USE OF ITEMS BASED ON RATINGS OF MINIMUM OR MORE

ITEMS	1	2	3	4	5	6	7	8	9	TOTAL OF EACH ITEM
Distress	34	18	38	25	19	37	3	24	3	201
Depression	30	12	28	13	18	36	—	8	1	146
Retardation	34	14	22	4	6	32	—	8	1	121
Agitation	26	14	13	13	22	31	2	5	1	127
Crying	—	1	4	—	1	1	—	3	—	10
Inability to cry	2	—	—	1	2	3	—	1	—	9
Anxiety	36	15	8	13	27	31	3	7	1	141
Anger expressed	5	1	10	—	12	13	—	—	—	41
Withdrawal	24	2	16	2	6	43	—	—	—	93
Pain	29	8	31	17	15	28	4	14	3	149
Weakness	12	5	20	8	9	25	3	7	—	89
Nausea	1	—	—	—	—	15	—	—	—	16
Swallowing	1	—	4	2	—	16	—	—	—	23
Other	—	—	1	—	—	10	1	2	—	14
Heartburn	—	—	1	—	1	1	1	1	—	5
Indigestion	—	—	—	—	1	3	—	—	—	4
Gas	—	—	—	1	1	1	—	—	—	3
Other	—	—	—	—	1	4	—	—	—	5
Constipation	1	1	—	4	3	14	—	1	—	24
Diarrhea	1	—	—	2	1	—	—	—	—	4
Urination	—	—	—	—	2	11	—	—	—	13
Other	—	—	—	—	2	—	—	—	—	2
Relates to patients	17	13	30	21	19	50	11	5	—	166
Improvement	7	2	2	7	1	25	—	10	—	54
Total use of items	260	106	228	133	169	430	28	96	10	
Number ratings by rater	68	37	49	62	54	57	14	81	29	

Table II is a gross picture of the use made of the scale. The numbers 0 to 5 depict the range from 0, none, through 5, the maximum.

TABLE II. RATER'S USE OF RESPONSE CHOICES DURING FIRST TRIAL PERIOD, JUNE 18-JULY 2, 1959

RANGE	CHOICES								TOTAL
	1	2	3	4	5	6	7	8	
5	0	1	0	0	0	3	0	0	4
4	11	1	8	0	2	3	0	0	25
3	17	2	29	2	4	18	1	0	73
2	30	11	13	10	10	13	10	5	102
1	30	23	27	17	10	29	16	1	153
0	403	488	325	189	309	366	235	17	2,332

Raters tended to use the conservative end of the scale, especially 1 through 4 (minimum, minimum-to-moderate, moderate, moderate-to-maximum). The high proportion of 0 or "none" ratings was contributed to by the newness of the instrument. Raters often commented that when they did not understand a dimension correctly, or had not observed the individual in respect to a particular dimension, a "none" was recorded. In addition, a "none" choice may be attractive as the easiest decision.

The remarks section contained frequent qualifying comments on specific choices and seldom offered general references. For instance, on June 29, Mrs. T. was rated "withdrawal, minimum." The remark, "less socializing since no roommate," qualifies the degree of her withdrawal. Another example was June 18 with Mrs. B. She was rated "retardation, minimum-to-moderate," with the remark "stayed in bed more than usual—husband did not visit."

Rater's Comments and Suggestions.—The form was described by different raters as "excellent," "a good thing," "concise," "saving time," "made sense," "helpful," "pretty good," "useful"; and it was also described as "monotonous," "of no benefit to nurses," "giving the impression of checking the same thing day to day," and "too repetitious." Some raters said it improved staff observation, more was learned about the patients, and the form was preferred over progress notes as simpler and more informative. Others indicated they did not learn anything new, they preferred progress notes, and the form was a chore. There was no evidence of marked dislike, however, and the degree of cooperation and interest was encouraging.

The following points were very useful:

1. There was a general consensus that the items on the form brought observations to mind that might have been forgotten in recording progress notes. The raters concurred that they were more observant when they knew the form required filling in at the end of the shift.

2. Preference for the form did not exclude progress notes. One rater stated, "There should be one place to record these things and that is in the nurses' notes; also, the nurses' notes should contain all the factors listed on the form."

3. A consistent criticism of the form was its lack of availability to subsequent shifts. Progress notes were available, but in order to control rater suggestibility, the form was removed from the chart after each shift.

4. Time for recording was an important consideration. One rater who considered the form a chore said it took 20 minutes. Generally, the raters described the time in proportion to the additional remarks. That is, when the patient presented the "usual" picture, it took 2 to 3 minutes to fill in. If several remarks were required, it usually took more than 5 minutes. It would take much more time in thought and writing of progress notes to record information comparable to that contained on the form.

5. The raters indicated that the items were comprehensive and they had no additions to suggest. Several improvements and possible deletions to reduce repetition were offered:

a. There was general confusion and difficulty in using "withdrawal" and

"relates to other patients." This difficulty emphasized the value of subheadings here as well as in other items.

b. Some raters were sensitive to the term "anger expressed," and preferred the less forceful description of "irritability," or "temper."

c. The various gastrointestinal items were considered useful reminders. However, these items were not used often enough (Table I) to warrant individual spaces. It was suggested they be listed as "other difficulties."

6. The scale—none, minimum, minimum-to-moderate, moderate, moderate-to-maximum, maximum—was considered satisfactory by the raters and of sufficiently wide choice to determine degree.

In terms of future use of a revised form, there were interest and motivation with some qualification. The raters thought continued use would improve staff observation and contribute to patient care and the research goal. Several raters suggested it be used instead of progress notes. One rater suggested it be substituted for progress notes with one group of patients, then compared with a group recorded on progress notes over the same time period. It was suggested that the person who had the most contact fill it out; or that all team members make recorded observations in the chart; or that the form represent a composite of observations by team members, since the team leader might not have sufficient contact with patients to take on responsibility at all times for complete recording.

Investigators' Decision and Formulations.—The form presented in Fig. 5 was developed after consideration of the previous information and consultation with other researchers. We had accumulated knowledge about this approach to recording; so to convey this to future raters the instructions were elaborated and placed on the back of the form for quick reference. In addition, a rater should be "trained" prior to rating. Some briefing had been carried out before the initial trial periods. However, rater No. 9 was assigned as "team leader" during the head nurse's absence and continued to rate without formal orientation. She admitted handling this by marking the "none" column for the most part (Fig. 4).

The number of items was reduced to achieve less repetition and greater attention to each item. "Socialization" and its scale represent the major single change. This evolved out of confusion and difficulty about "withdrawal" and "relates to other patients." Several references were reviewed in the sociological literature[18-21] that contributed to its development.

A change considered particularly useful by the raters was the rearranging of synonyms under each item in such a manner that an additional scale for determining intensity was included. For example, on the "retardation" item, "tired" would probably receive a minimum or minimum-to-moderate rating as compared to "forgetful" or "deteriorated," which would probably be moderate-to-maximum or maximum. This was designed as a guide and not a rule.

CONCLUSION

This paper demonstrates an approach to the task of recording and quantifying emotions and behavior of patients hospitalized for metabolic study. There is evidence in the investigation that this method can supply a base-line standard for recording the social-emotional variables involved.

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SYMPTOM AND BEHAVIOR OBSERVATIONS

NAME: DATE: RATER & SHIFT:	none	minimum	minimum to moderate	moderate	moderate to maximum	maximum	REMARKS
DISCOMFORT-from any cause, uneasy, troubled, strained, stress, distress, suffering, misery, agony							
DEPRESSION-feeling bad, let down, moody, slouched, sad, blue, unhappy, sulky, gloomy, feeling lousy, apathetic, depressed, dejection, melancholy							
RETARDATION-slowing down of physical and/or mental activities, weary, tired, slowed speech, lazy feeling, increased bedrest, nonambulatory, forgetful, deteriorated							
IRRITABILITY-nagging, whining (TV, unit, procedures, apparatus), complaining (study), frowning, annoyed, pouting, touchy, irritable, peeved, sarcastic, angry, anger expressed							
AGITATION-unsettled, disordered, restless, shaky, excited, wringing hands, tossing and turning							
ANXIETY-fearful, tense, jittery, nervous							
PAIN-any physical complaint about pain such as back, head, neck, arm							
WEAKNESS-fatigue							
CRYING							
OTHER DIFFICULTIES (circle)-nausea, swallowing (taking pills), too much to eat, hungry, heartburn, indigestion, gas, constipation, diarrhea, urination, other							
DEGREE OF IMPROVEMENT-expressed spontaneously by patient							
EXPRESSIONS OF CHEERFULNESS-smiles, laughs, happy, gay, light hearted, carefree, euphoric							
for socialization observation only →	never	seldom	occasionally with difficulty	frequently	almost constantly	constantly	
SOCIALIZATION (new scale) with patients and/or staff: visits, chit-chats, walks, seeks company							

INTAKE/OUTPUT RECORD:

Fig. 5,A.—Improved form and instructions for recording symptom and behavior observations.

The approach is to help observers record observations made in their contacts with patients. The instrument is new, but the words, ideas, and concepts are gleaned from nurses' progress notes, their comments in staff meetings, and their suggestions. This was specially designed for one nursing unit and group of observers. It was not founded on a method and design proved in another setting and imposed on this one and its raters. It evolved out of current practice. It is conceivable that on another nursing unit with different raters there might be differences in expressions used to convey observations. For instance, the concept

INSTRUCTIONS

General:

1. This form is designed to record a composite of observations by team members on a patient during a particular nursing shift. It should be based on observations during one shift and be kept independent of recordings and observations of other shifts.

2. After completion of the form, place it in the medical chart or as directed by the Head Nurse.

Scale:

1. It is important to place a mark in the appropriate column for *each* descriptive term. There should not be any "blanks."

2. It is important to record any amount of symptoms and behaviors on the scale, even if it is observed for a short time.

3. Socialization is the only dimension having its own scale.

Dimensions or descriptive terms:

1. There are 13 dimensions, each important in describing the patient. Consider each one carefully. The first form contained 24 items and there was a tendency to skim through the list. This form represents a reorganization designed to encourage careful, thoughtful consideration of each dimension by the observer.

2. Wherever possible, the words or synonyms placed under each dimension (e.g., Agitation-unsettled, disordered, etc.) are listed in a graduating order that the rater may use as a guide in determining intensity on the scale. For example, "tired" is probably a less retarded sign that "forgetful" or "deteriorated."

Remarks:

The remarks column can be used in any way the rater wishes—clarifying or qualifying descriptive terms, quoting patients, adding observations not covered by the list provided, suggestions regarding the form or the patient, anything. Special situations or incidents such as deaths on the unit, trouble or special events in the patient's family, transfer of doctors or change in personnel, should be noted. Your comments will be useful and appreciated.

Fig. 5, B.—(*For legend see opposite page.*)

of depression might be more specific to personnel in a psychiatric setting than it was in our experience. The general framework and the use of a form would probably remain.

Through the use of a limited sample during a 2 week, then a 2 month trial period, stress after admission was demonstrated. A concurrent picture of social-emotional response and changes during the course of a single blind study involving a period of placebo, period of experimental drug, and again a period of placebo was obtained. The impact of deaths on the medical unit was registered; and the reaction to a change of physicians elicited. It is relatively simple to use and retain, and can be programed on IBM cards for specific reference at any time. This is meaningful in metabolic studies where physiologic analysis takes months or years to complete. The determination of whether an unexplainable physiologic finding could have been distorted by some social-emotional factor cannot be determined without such a record. The test of whether such a record can determine degree of influence must await the availability of the laboratory data.

Involvement of the staff was described. The nursing staff expressed increased alertness to their patient's emotions and behavior. This produced more of a focus on the total individual in addition to his metabolic nourishment, stools, emesis, and urine collections. Some of the patients' and staff's tensions were

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reduced. There was increased interest in research in general, in the metabolic study regime, and in our study in particular.

A follow-up is planned to enlarge on the findings, to test some of the foregoing implications, and to test the reliability of the observational instrument. The revised form will be used on a larger sample over a longer period of time. Ultimately, it is planned to correlate the data derived through the instrument with calcium balance data and possibly with balance data on nitrogen and phosphorus. The possibility of utilizing other patient groups on the same nursing unit, or attempting similar studies on other units and in different settings has been discussed.

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Medical Care

THE QUALITY OF MEDICAL CARE: TECHNIQUES AND INVESTIGATION IN THE OUTPATIENT CLINIC

ROBERT R. HUNTLEY, M.D.,
RAHEL STEINHAUSER, R.R.L.,
KERR L. WHITE, M.D.,
T. FRANKLIN WILLIAMS, M.D.,
DAN A. MARTIN, M.D., AND
BERNARD S. PASTERNACK, PH.D.

CHAPEL HILL, N. C.

From the Departments of Preventive Medicine and Medicine, School of Medicine, and Department of Biostatistics, School of Public Health, University of North Carolina

(Received for publication Feb. 26, 1961)

ALMOST all medical care is given outside the confines of hospital wards but, to date, little effort has been made to evaluate or control the quality of care being delivered to these ambulatory patients. It seems particularly important for the staff of a university hospital's teaching clinic to investigate means of examining and measuring those elements of contemporary medical practice which are believed to reflect, at least in part, the quality of care of ambulatory patients. The staff not only gives medical care, but it also sets the arbitrary standards against which students and house staff educated in the clinic may compare their own present and future performances. The present study represents a critical attempt to devise methods of studying those aspects of medical care that would indicate, at least to a limited extent, the "quality" of that care.

"Quality" is difficult to define when related to the complexities of medical care, and, in the final analysis, absolute standards can be defined only in relation to levels of individual and community health. Nevertheless, as a first effort in this direction a group of physicians can define standards for its own performance, against which to compare its actual achievement. These arbitrary standards, as well as their ultimate relationships to individual and collective health, require continuing study and refinement.

One practical approach to assessing the quality of medical care has been through the systematic study of medical records.[1,2] While it is recognized that medical records do not necessarily reflect the quality of care given by an individual or an institution, they are tangible evidence, in accessible form, of the kinds of care given.

Supported in part by a Research Grant (W-74) of the United States Public Health Service.

THE CLINIC CHART CONFERENCE AND PRELIMINARY INVESTIGATIONS

Previous studies have shown that periodic examination of *inpatient* records, with the return of deficient records to the responsible physician for completion, is a relatively effective means of maintaining records of satisfactory quality.[2] An analogous system for examining *outpatient* records was introduced in 1953 in the General Clinic of the North Carolina Memorial Hospital, the principal teaching clinic of the Departments of Medicine and Preventive Medicine in the University of North Carolina Medical School.[3] A weekly chart conference is held, attended by senior physicians responsible for the operation of the Clinic, by Clinic resident physicians, and by a research medical records librarian. The charts of all patients seen in the General Clinic are reviewed at this chart conference 4 weeks after the initial work-ups, to determine whether the criteria for an adequate work-up have been met. If they have not, the chart is returned to the responsible physician or student for completion and is recalled to the chart conference at a later date.

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In this Clinic it is believed that the record of an initial medical work-up of superior quality should include a complete history and physical examination, a routine hemogram, urinalysis, serologic test for syphilis, screening chest x-ray, rectal examination of all males, rectal and pelvic examination, with cervical Papanicolaou smear, of all females, and stool examination for occult blood of all patients. The charts of patients worked up by students also should include a preceptor's note, reviewing the history and physical examination and evaluating the patient's problem. The preceptor devotes approximately 2 hours to the supervision of a single student with his new patient.

It is further believed that, if abnormalities in any of these areas are recorded, they should be properly evaluated and followed up. All diagnoses should be supported by documentary evidence in the chart. Adequate plans for the patient's continuing care should be recorded. A copy of the letter sent to the family physician when the patient is discharged from the Clinic should be filed in the chart. This letter should include a summary of all positive findings, diagnoses, and recommendations for further management, so that the family physician can resume responsibility for the patient with all the information he requires for maximum effectiveness. Such a letter is particularly important in this Clinic, which serves largely as a consultation center for physicians in the eastern two thirds of North Carolina.

A. Identification of Deficiencies.—Because the weekly chart conference is the primary means by which the Clinic staff attempts to monitor quality, it seemed important to attempt a critical evaluation of the efficiency and effectiveness of this conference. A preliminary study was designed to discover which types of deficiencies in the charts were not being regularly detected and corrected, so that special attention could be given to these areas.

A 20 per cent representative, random sample of the 600 new patient work-ups performed by students during the Spring of 1959 was analyzed. Work-ups by students were chosen because of their educational importance and because they presumably represent the optimal care available in this Clinic. This sample included four charts of each student in the General Clinic. These charts had been

"approved" at chart conference and were considered "satisfactory" by the physicians reviewing them.

Table I summarizes the omission rates and the incidence rates of selected abnormal findings per 100 work-ups. Criteria for abnormality are listed in the left-hand column of the table. These are routine *clinical* determinations, which are supposed to be obtained on every patient (except as noted), either by the Clinic nurse or the medical student. Omission rates are listed in the middle column. It will be noted that some "routine" determinations, such as temperature, pulse, and blood pressure, rarely are omitted, whereas other procedures, some "routine," such as measurement of height and weight, and some requiring special effort, such as proctoscopy, are omitted quite frequently. The rates for abnormalities in these determinations are listed in the right-hand column of Table I.

TABLE I. ANALYSIS OF SELECTED ROUTINE CLINICAL DATA, 1959 (OMISSIONS AND ABNORMALITIES EXPRESSED AS RATE PER 100 WORK-UPS. N = 120; 20 PER CENT SAMPLE)

DETERMINATION	UPPER LIMITS OF NORMAL	OMISSIONS	ABNORMALITIES
Temperature	99.9°F.	6	0
Pulse	110 per minute	0	2
Systolic blood pressure	160 mm. Hg	0	27
Diastolic blood pressure	90 mm. Hg	0	41
Weight	Males 180 pounds Females 150 pounds	13	26
Height	—	24	—
Rectal and/or pelvic*	—	4	15
Proctoscopic†	—	67	17

*Not indicated in teen-age, unmarried girls without rectal or pelvic complaints (7 in this sample).
†Not indicated in patients under 40 without gastrointestinal complaints (47 in this sample).

Because an elevated diastolic blood pressure was the most frequently observed abnormality on physical examination, it was decided to evaluate the attention given this finding, as demonstrated by the kind of work-up done and the final diagnosis. So that results would be more meaningful, the only charts examined were those of patients whose diastolic blood pressures were recorded as 100 mm. Hg or greater. In this group of 25 patients, 7, or almost one fourth, had had no special tests directed toward either the cardiovascular or renal systems. That is to say, a repeat urinalysis, blood urea nitrogen determination, electrocardiogram, cardiac fluoroscopy, circulation time or venous pressure determination had *not* been performed. Twelve of these 25 patients with diastolic hypertension had neither primary nor secondary diagnoses in the cardiovascular system. These observations suggest that not enough attention is given to this finding in many patients seen in the Clinic.

The criteria for defining "abnormal" laboratory determinations are listed in the Appendix. Table II summarizes the findings with regard to certain routine *laboratory* data. In the left-hand column, it is seen that the hemogram and urinalysis were omitted only once per 100 work-ups, whereas an omission rate of 50 per 100 was observed for the stool benzidine test and 25 per 100 for the screening chest x-ray. The middle column of Table II lists the incidence of abnormal

findings in these determinations. However, the most important observation is the large number of abnormal findings (right-hand column) not followed up, in so far as could be determined from a careful examination of the clinical record. These high omission rates and the high incidence of abnormalities not followed up probably come as no surprise to anyone who has attempted chart studies, but it does reflect an undesirable lack of thoroughness. They indicate that, although the Clinic chart conference was conducted as thoroughly as any *inpatient* chart conference with which the authors are familiar, it still was not doing an efficient job of detecting and correcting chart deficiencies.

B. Revised Clinic Chart Conference Procedure.—These preliminary studies led to a reorganization of the chart conference procedure with the assignment of specific duties to the record librarian and to the reviewing physicians. An "activities card" (Fig. 1, *A* and *B*) was designed for recording pertinent data, including the deficiencies in the work-ups which seemed to be most important on the basis of the preliminary study.

TABLE II. ANALYSIS OF CERTAIN ROUTINE LABORATORY DATA, 1959* (OMISSIONS AND ABNORMALITIES ARE EXPRESSED AS RATES PER 100 DETERMINATIONS. N = 120; 20 PER CENT SAMPLE)

DETERMINATION	OMISSIONS		ABNORMALITIES		ABNORMALITIES NOT FOLLOWED UP	
	RATIO	RATE	RATIO	RATE	RATIO	RATE
Hemogram	1/120	1	27/119	23	4/27	15
Urinalysis	1/120	1	30/119	25	16/30	53
Screening chest x-ray	30/120	25	27/90	30	1/27	4
Serologic test for syphilis	2/120	2	6/118	5	0/6	0
Cervical Papanicolaou smear	9/54†	17	2/45	4	0/2	0
Stool benzidine test	56/113‡	50	2/57	4	0/2	0
Mean rates	99/647	15	94/548	17	21/94	22

*Standards for hemogram and urinalysis in this preliminary study were somewhat more lenient than those currently in use. Current standards are cited in the Appendix.

†This test was indicated on 54 females in this sample of 120 patients.

‡This test was considered "not indicated" on 7 teen-age, unmarried females in this sample, because pelvic and rectal examination was not done, and no specimen was available.

The record librarian initiates an activities card for each chart to be reviewed. She indicates on the margin of the card deficiencies and abnormalities in the routine clinical and laboratory work-up and notes the disposition made of the patient and whether the summary discharge letter to the referring physician has been sent. The reviewing physician then examines each deficiency or abnormality noted, evaluates the adequacy of the entire work-up and disposition, and records and codes the diagnoses for entry in the hospital diagnostic index.[4] Any chart with unexplained omissions or abnormalities in history, physical examination, laboratory work, or disposition is returned, with an explanatory note, to the responsible student or physician for completion, and reviewed again in chart conference 2 weeks later. The activities card is filed by semester and by

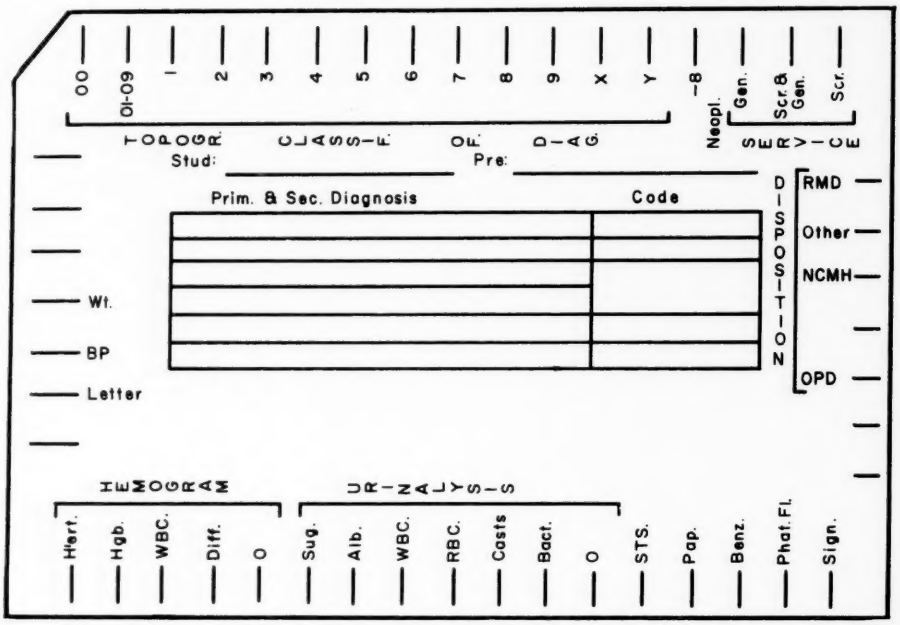

Fig. 1*A*.—Front of "activities card".

primary diagnosis for use in further studies of quality and performance in the Clinic.

A major reason for making these changes in the chart conference procedure was to make the follow-up of routine abnormalities in the laboratory work more mechanical, so that the physicians who work in this conference would have more time to study charts in detail, particularly from the standpoint of the amount of attention given to patients' presenting problems and final dispositions. This implies careful scrutiny of the history, physical examination, progress notes, and "nonroutine" laboratory determinations, and a subjective conclusion that all the chart data, taken together, form a coherent, logical description of the patient, his problems, their investigation and management.

EVALUATION OF REVISED CLINIC CHART CONFERENCE

The present study was designed to assess the influence of the revised chart conference procedure on the adequacy of the follow-up of *laboratory* abnormalities. These abnormalities were chosen for this initial study because it is easier to obtain reasonably objective quantitative data in this area. It was believed that any change noted in the thoroughness with which this portion of the follow-up was conducted would be a reliable indication of the effect of changes in the chart conference procedure on the over-all quality of the clinical record. This hypothesis will require testing by the application of similar procedures to other portions of the record.

A. Procedure.—Two 40 per cent representative, random samples of 240

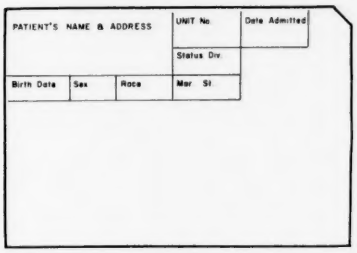

Fig. 1*B*.—Back of "activities card".

charts each were drawn from all work-ups of new patients completed by the 60 senior students in the General Clinic during the Spring semesters of 1959 and 1960. One sample was taken before, and one after, the revised chart conference procedure was instituted on Jan. 1, 1960. The 480 charts in the samples were examined from 3 to 18 months after the completed work-ups had been approved by the Clinic chart conference. All activities cards were rechecked against the 1960 charts, similar cards were prepared for the 1959 charts, and the data analyzed.

B. Results.—Table III summarizes certain demographic data and Table IV, the principal diagnostic categories of the two samples, which are comparable to each other and to previous samples drawn from the General Clinic population.[5,6]

TABLE III. DATA ON AGE, RACE, AND SEX

RACE, SEX	AGE				TOTAL
	BELOW 20	20-40	40-60	OVER 60	
1959 Sample (40%)					
White male	0	21	37	16	74
White female	4	27	37	17	85
Non-white male	1	13	18	7	39
Non-white female	3	13	13	13	42
Total	8	74	105	53	N = 240
1960 Sample (40%)					
White male	6	11	33	16	66
White female	6	33	29	13	81
Non-white male	2	13	21	8	44
Non-white female	8	22	14	5	49
Total	22	79	97	42	N = 240

	1959	1960	TOTAL N = 480
Totals, all ages			
White	159	147	306
Non-white	81	93	174
Male	113	110	223
Female	127	130	257

TABLE IV. TOPOGRAPHIC DIAGNOSTIC DATA.* PRIMARY DIAGNOSES, 1959 AND 1960 (40 PER CENT SAMPLE EACH YEAR)

CATEGORY	1959		1960		TOTAL	
	NO.	%	NO.	%	NO.	%
Psychobiologic 00	62	26	49	20	111	23
Body as a whole 01–09	11	5	9	4	20	4
Integumentary 1	7	3	7	3	14	3
Musculoskeletal 2	13	5	30	13	43	9
Respiratory 3	13	5	22	9	35	7
Cardiovascular 4	41	17	33	14	74	16
Hemic and lymphatic 5	2	1	5	2	7	2
Digestive 6	35	14	23	10	58	12
Urogenital 7	8	4	18	7	26	5
Endocrine 8	15	6	16	6	31	6
Nervous 9	23	10	24	10	47	10
Organs of special sense x and y	10	4	4	2	14	3
Total	240	100	240	100	480	100

*According to *Nomenclature of Disease and Operations.*[4]

Table V shows comparative data for the 1959 and 1960 samples. The incidence of patients with abnormalities not followed up showed a decrease from 60 to 40 per 100 ($P < .01$), and the incidence of individual abnormalities not followed up decreased from 34 to 23 per 100 ($P < .01$). Because the student, preceptor, and the patient populations appear comparable, and the most significant recognizable change was a refinement in the Clinic chart conference procedure, it seems probable that the lower incidence of abnormalities not followed up in the 1960 sample is related to this refinement.

Table VI examines (a) individual abnormalities and (b) individual omissions. Improvement is noted in every category except serologic tests for syphilis, where omission rates were higher in 1960. In some categories, the numbers are small and conclusions unwarranted. However, the improved rates of follow-up for all abnormalities and the smaller number of stool benzidine tests and screening chest x-rays omitted ($P < .01$) is further evidence that refining the Clinic chart conference procedure probably has resulted in more complete and adequate follow-up of routine laboratory procedures.

Considerably more improvement should be possible. For example, 138 of the 480 patients in the two samples had no stool benzidine examination recorded.

TABLE V. SUMMARY OF LABORATORY ABNORMALITIES, 1959 AND 1960 (N = 240 PATIENTS EACH YEAR; 40 PER CENT SAMPLE EACH YEAR)

	1959	1960
Patients with one or more abnormalities or omissions not followed up	135	89
Total patients with abnormalities or omissions	226	224
Rate of abnormalities or omissions not followed up per 100 patients with abnormalities or omissions	60	40 ($P < .01$)
Individual abnormalities not followed up	115	88
Total individual abnormalities	343	376
Rate of abnormalities not followed up per 100 individual abnormalities	34	23 ($P < .01$)

TABLE VI. INDIVIDUAL LABORATORY ABNORMALITIES* AND OMISSIONS† (N = 240 PATIENTS EACH YEAR; 40 PER CENT SAMPLE EACH YEAR)

	1959		1960		P (CHI^2)
	RATIO	RATE	RATIO	RATE	
Abnormalities Not Followed Up					
Hemogram	68/129	53	47/137	34	<0.01
Urinalysis	42/115	37	37/153	24	<0.05
Serologic test for syphilis	1/7	14	0/8	0	N. S.
Papanicolaou smear of cervix	0/5	0	0/4	0	N. S.
Stool benzidine test	2/11	18	0/11	0	N. S.
Screening chest x-ray	2/76	3	4/63	6	N. S.
Mean	115/343	34	88/376	23	<0.01
Procedures Omitted					
Serologic test for syphilis	1/240	0.4	8/240	3	<0.05
Papanicolaou smear of cervix	9/127	7	4/130	3	N. S.
Stool benzidine test	88/240	37	50/240	21	<0.01
Screening chest x-ray	16/240	7	3/240	1	<0.01
Mean	114/847	13	65/850	8	<0.01

$$\text{*Rate of abnormalities not followed up} = \frac{\text{Abnormalities not followed up}}{\text{Total abnormalities}} \times 100.$$

$$\text{†Rate of procedures omitted} = \frac{\text{Procedures omitted}}{\text{Procedures indicated}} \times 100.$$

Although it is believed that many of these benzidine tests were performed by the students but not recorded on the charts, this is of no benefit to these patients and their physicians if they return for further examination at a later date. Eleven of the 254 females had no Papanicolaou smears of the cervix reported. Two additional patients had unsatisfactory Papanicolaou smears that were not repeated. The discovery of 5 carcinomas of the cervix in the 254 females who appear in these two samples emphasizes the potential seriousness of omitting this test.

In Table VII, abnormalities not followed-up are related to the class standing of the students doing the work-ups, as determined by their positions in the upper, middle, and lower thirds of their class, based on National Board Examination (Part II) scores and an evaluation of clinical competence by teachers in the senior year. Although there is a slight downward gradient from the upper to the lower third of the class, when class standing is compared with performance in following up laboratory abnormalities, this is not statistically significant in either year's sample. There was improvement in all three groups between 1959 and 1960, with the upper third showing the most improvement. The differences in rates of improvement among the three student groups are not great, but they do suggest that more rigorous auditing of charts may have had a greater influence on the better students, although all three groups appeared to respond to this stimulus.

TABLE VII. CLASS STANDING OF STUDENTS COMPARED WITH THE RATE OF LABORATORY ABNORMALITIES NOT FOLLOWED UP (N = 240 PATIENTS EACH YEAR; 40 PER CENT SAMPLE EACH YEAR)

CLASS STANDING	1959		1960		P (CHI^2)
	RATIO	RATE	RATIO	RATE	
Upper third	45/77	58	26/80	33	<0.01
Middle third	48/82	59	38/85	45	N. S.
Lower third	42/67	63	25/59	42	<0.05
Mean	135/226	60	89/224	40	<0.01

There are five types of preceptors in the General Clinic, as listed in Table VIII. The "resident and fellow" group comprises "house staff" preceptors; "part-time medicine" comprises the internists and family physicians who are in private practice in nearby communities and who spend one-half day per week teaching in the Clinic; "full-time medicine" comprises the subspecialists within the Department of Medicine, exclusive of the "core group"; the "psychiatrists" are precepters with regular medical patients, and all have had considerable training in internal medicine as well as in psychiatry. The core group comprises the seven full-time staff members of the Departments of Medicine and Preventive Medicine who have a major responsibility for education, research, and service in the General Clinic.

The data in Table VIII show the variation in adequacy of follow-up among the five preceptor groups. All groups, except psychiatrists, showed improvement from 1959 to 1960, but the 34 cases of which psychiatrists were preceptors represent too small a group from which to draw conclusions.

Table IX relates the adequacy of follow-up to distance from the patient's home to the hospital, the patient's race, and the patient's primary diagnosis. Only one of these factors appeared to influence the incidence of abnormalities not followed-up. In the 1959 sample there was a higher incidence of abnormalities not followed-up among the patients whose primary diagnoses were "psychobiological" compared with all other diagnoses ($P < .01$). In the 1960 sample this dif-

TABLE VIII. TYPE OF PRECEPTOR COMPARED WITH THE RATE OF LABORATORY ABNORMALITIES NOT FOLLOWED UP (N = 240 PATIENTS EACH YEAR; 40 PER CENT SAMPLE EACH YEAR)

TYPES OF PRECEPTORS	1959		1960		P (CHI²)
	RATIO	RATE	RATIO	RATE	
Residents and fellows	35/69	51	34/92	37	N. S.
Part-time medicine	27/43	63	22/60	37	<0.05
Full-time medicine	18/29	62	12/34	35	<0.05
Psychiatrists	18/25	72	7/9	78	N. S.
Core group	37/60	62	14/29	48	N. S.
Mean	135/226	60	89/224	40	<0.01

ference was no longer present, suggesting that patients without clinically obvious organic disease benefited most from more systematic chart review.

Reassurance that these attempts at developing methods for quality control are not focused solely on trivia is found when the data are re-examined from the standpoint of grossly abnormal laboratory findings, as defined at the foot of Table X. The data on this table indicate that grossly abnormal findings, which were not followed-up or explained in any way, were recorded in the charts of 64 of the 480 patients in this study, or 13 per cent. These included 6 positive screening chest x-rays and 2 benzidine-positive stool specimens. They also included a white blood count of 3,100, a hemoglobin level of 9 Gm., a urinary sediment containing 10 to 15 pus cells and bacteria, and many other similar, potentially serious abnormalities.

Data on the follow-up of elevated diastolic blood pressure, cited earlier, suggest that failure adequately to evaluate abnormalities is not limited to laboratory findings. Further study of these problems, as related to the history and physical examination, is currently under way.

It is anticipated that the data on the activities cards may be useful in monitoring the effectiveness of specific teaching exercises in the Clinic. Further development of techniques such as those described ultimately may result in specific indices of quality of medical care which can be used in the continuous monitoring of a Clinic's service and teaching activities. It seems clear from the data presented that continuous monitoring is needed in the Clinic studied. If other outpatient departments were to employ similar approaches to their problems, similar needs might be apparent. The application of techniques such as those presented here in other clinics should improve the quality of care provided and hasten the development of generally acceptable standards for care of ambulatory patients.

SUMMARY

Some stages in the evolution of chart conference procedures currently in use in the General Clinic of the North Carolina Memorial Hospital are described, together with an analysis of data from two representative, random samples of

TABLE IX. DISTANCE, RACE, AND PRIMARY DIAGNOSIS COMPARED WITH THE RATE OF LABORATORY ABNORMALITIES NOT FOLLOWED UP (N=240 PATIENTS EACH YEAR; 40 PER CENT SAMPLE EACH YEAR)

	1959		1960	
	RATIO	RATE	RATIO	RATE
Distance				
1– 50 miles	39/58	67	23/59	39
50–200 miles	69/119	58	50/124	40
200+ miles	27/49	55	16/41	39
Mean	135/226	60	89/224	40
Race				
White	93/151	61	52/132	39
Non-white	42/75	56	37/92	40
Mean	135/226	60	89/224	40
*Primary Diagnoses**				
"Psychobiologic"	47/57	82†	18/44	40
All other diagnoses	88/169	52†	71/180	39
Mean	135/226	60	89/224	40

*According to *Nomenclature of Disease and Operations.*[1]
†Difference between these two rates is significant ($P < .01$).

TABLE X. GROSSLY ABNORMAL FINDINGS NOT FOLLOWED UP* (N=240 PATIENTS EACH YEAR; 40 PER CENT SAMPLE EACH YEAR)

ABNORMALITY	1959	1960	TOTAL
Hemogram	14	10	24
Urinalysis	19	17	36
Serologic test for syphilis	1	0	1
Stool benzidine test	2	0	2
Screening chest x-ray	2	3	5
Total abnormalities	38	30	68
Total patients	36	28	64

*Grossly abnormal, for purposes of this analysis, is defined as follows:

Hemogram:
- Hematocrit less than 35% or greater than 55%.
- Hemoglobin less than 10 Gm. or greater than 17 Gm.
- WBC less than 4,000 or greater than 14,000.
- Differential, lymphocytes more than 50%; eosinophils more than 7%.

Urinalysis:
- Sugar, any.
- Albumin, 1+ or more.
- WBC, more than 10 per high-power field.
- RBC, 4 or more per high-power field.
- Bacteria, not called abnormal unless present with some other finding, i.e., albuminuria, pyuria, etc.
- More than 1 of the above abnormalities.

Serologic test for syphilis: Positive.
Stool benzidine test: Positive.
Screening chest x-ray: Positive.

student work-ups during the Spring semesters of 1959 and 1960. These data suggest the value of developing and improving the efficiency of techniques in an ambulatory clinic which may be used to evaluate the quality of care being given. A method by which periodic surveys, using specially designed activities cards to detect areas needing further investigation or increased emphasis in the teaching program, is described. A major benefit of monitoring the quality of medical care in an outpatient clinic may be the awareness encouraged in students and staff that attention to detail in evaluating and recording clinical data is part of their responsibility as physicians.

Appendix

PROCEDURE: ROUTINE QUALITY CONTROL IN THE GENERAL CLINIC OF THE NORTH CAROLINA MEMORIAL HOSPITAL

I. Purpose:
   A. To maintain continuing control of the quality of medical care given in the General Clinic.
   B. To maintain a card file of diagnoses, abnormalities, and deficiencies recorded in work-ups.

II. Procedure for Record Librarian:
   A. Four weeks after the initial General Clinic visit, the record librarian will reassemble each chart in proper order, check it for completeness and for abnormal findings in specific categories listed below, and initiate an activities card.
   B. A complete chart will consist of the following:
      1. Letter to referring physician signed by the preceptor or the house officer.
      2. Initial history and physical examination and follow-up progress notes signed by the student, intern, or resident doing the work-up.
      3. A final note stating the disposition of the patient if he is no longer being followed in the General Clinic.
      4. A record of routine laboratory procedures, i.e., hemoglobin, hematocrit, white count, differential, urinalysis, serologic test for syphilis, stool benzidine test, screening chest x-ray, and cervical Papanicolaou smear on female patients.
      5. Final letter to referring physician or agency, which should include diagnoses, clear recommendations for management, and final disposition of the patient.
   C. All deficiencies will be indicated by a red mark in the appropriate place along the margin of the activities card. The card will be attached to the front of the chart.
   D. Normal limits for laboratory determinations are[7]:
      1. Hemoglobin— Men: 14 to 16 Gm.
         Women: 12 to 16 Gm.
      2. Hematocrit— Men: 40 to 54 per cent.
         Women: 37 to 47 per cent.
      3. Differential count: lymphocytes (less than 40 per cent); eosinophils (less than 5 per cent); and monocytes (under 10 per cent).
      4. White blood count: between 5,000 and 10,000 cells per cubic millimeter.
      5. Urinalysis: no sugar or albumin. Microscopic examination is abnormal if white cells are over 3, red cells are over 1 per high-power field, there are any casts or bacteria. In the case of abnormal microscopic examination a repeat normal urinalysis is considered adequate follow-up.
      6. Serologic test for syphilis: negative.
      7. Cervical Papanicolaou smear: negative.
      8. Stool benzidine test: negative.
      9. Screening chest x-ray: negative. A repeat x-ray, with the use of large film and with clear disposition, constitutes adequate follow-up.

III. Procedure for Chart Conference:

A. After charts have been reviewed and activities cards have been completed by the record librarian, they will be brought to the Chart Conference. All charts will be reviewed by the physicians attending the Chart Conference with special attention given to those with deficiencies. This review will include a recheck of the routine work-up as well as some evaluation of its adequacy in relation to the data supporting the final diagnoses.

B. When a chart is judged satisfactory by the reviewing physician, he will record and code the primary and secondary diagnoses on the face sheet and date and sign this sheet. He will initial the activities card to indicate approval. Unsatisfactory charts are returned to the responsible student or physician for completion and will be recalled to Chart Conference 2 to 4 weeks later.

C. A Chart Conference Log will be maintained by the Record Librarian, showing the number of abnormalities detected, the number not followed up before the Chart Conference, and the types of abnormalities noted.

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RECREATIONAL AND WORK THERAPY ON A HOME CARE PROGRAM

I. ROSSMAN, PH.D., M.D., AND MARGARET CLARKE, M.A.

NEW YORK, N. Y.

From the Home Care Department, Division of Social Medicine, Montefiore Hospital, New York City

(Received for publication March 8, 1961)

Vol. 14
1961

THE plan of development envisioned at the inception of the Montefiore Hospital Home Care Program was to offer services paralleling those available to the hospitalized patient.[1,2,3] Accordingly, in addition to medical, nursing, and social work services it was felt that chronically ill patients unable to leave their apartments, and in some instances their beds, would need some kind of diversion or occupation. Soon after Home Care began in 1947, a program of recreation and art therapy was introduced to provide patients with diversion. In 1956 work activity was introduced through a research and demonstration project, Jobs for the Homebound. Thus we have had a unique opportunity to observe the reactions of a chronically ill, homebound population to recreation and work therapy and we report here some of our observations. This seems the more desirable because, in spite of the steady, albeit slow, growth of Home Care Programs, none have offered recreational and work therapy in a comparable fashion.

When recreation and art therapy was introduced it was found that some patients enthusiastically took up diversional pursuits, some were lukewarm in their acceptance, and still others negativistic. We also found a number of patients who strongly indicated that their preference was for work. One of these was S. S., 59 years old, a former tailor with aortic stenosis and chronic heart failure. His days were spent in an aimless and apathetic fashion, with little interest in proffered diversional therapy. Both he and his wife were depressed, irritable, and quarrelsome. A special arrangement with his former employer was worked out, and bundles of sewing were brought to the patient. This kept him busy for 4 or more hours per day and provided a significant income. The transformation was impressive to all the personnel attending him; he brightened up, became much more content, and even his relationship to his wife improved. In addition, his physician thought there was objective improvement in the over-all cardiac picture.

Unfortunately, the majority of Home Care patients who wished to work were too ill for admission to vocational rehabilitation facilities in the community.

This investigation was supported, in part, by a research and demonstration grant from the United States Office of Vocational Rehabilitation, Department of Health, Education, and Welfare, Washington, D. C. The New York Chapter of the Arthritis and Rheumatism Foundation, the New York Heart Association, and the Nathan Hofheimer Foundation also provided grants for the project.

Jobs for the Homebound was initiated for the purpose of exploring the vocational potential of Home Care patients who wished to work. The project has been described elsewhere.[4,5]

PATIENTS IN STUDY GROUP

Our Home Care patients, as described elsewhere, are almost entirely chronically ill, too sick or disabled to attend the clinic, and in need of continuing medical and nursing care. In a typical recent year (1958) 158 different patients were on Home Care and this is the sample we shall discuss. Of these, 60 were men (38 per cent) and 98 women (62 per cent). Ages ranged up to 89 with a median age of 64.

In order to simplify the analysis and in recognition of the importance of biologic as against chronologic age, patients with primarily atherosclerotic disease have been grouped together under the heading of vascular disease: 55 or 34.8 per cent of all our patients fell into the vascular disease category, which included strokes, peripheral vascular disease, hypertensive cardiovascular disease, and diabetes with predominantly vascular complications. Diagnostic categories of the remaining patients were cancer, 30 patients (19 per cent); pulmonary disease, chiefly pulmonary insufficiency, 18 (11.3 per cent); arthritis, 17 (10.7 per cent); heart disease, generally chronic failure, 13 (8.2 per cent). Twenty five (16 per cent) patients had miscellaneous diagnoses including neurological disorders, renal insufficiency, lupus erythematosus, and cirrhosis.

It was found convenient to divide the patients into three disability groups for purposes of analysis:

Group I contained 30 patients (19 per cent). It consisted of patients who, though disabled, were not usually in pain or subject to discomfort. Among them for example, were homebound cardiac patients in chronic heart failure but with reasonable compensation, and patients with diabetic nephropathy or lupus erythematosus. Group I patients could occasionally get out of doors and could be transported to the hospital without significant difficulties.

Group II, which contained the greatest number of patients, 75 (48 per cent), consisted of those who had moderate discomfort 50 per cent or more of the time and continuing disability with regard to carrying out activities in the home. This included many of our patients with arthritis who had pain on ambulation, some with asthma and pulmonary insufficiency, cardiac patients with dyspnea on slight-to-moderate effort, others with residual hemiplegias, and still others with peripheral vascular disease with some pain on ambulation though not necessarily while resting.

Group III contained 53 (33 per cent) patients. They could do relatively little about the house, frequently had discomfort, and in some cases had pain which was virtually continuous. These patients had a marked constant disability or symptoms which interfered with functioning even at rest. They included those with severe arthritis, far-advanced cancer, severe pulmonary insufficiency, peripheral vascular disease with rest pain, and the like.

The socioeconomic status of most patients was lower or lower-middle class.

None had sufficient income to pay for the extensive medical services they required. Prior to illness most had worked at semiskilled or unskilled jobs. Many of the patients were foreign born or had immigrated to this country at an early age. Because of poverty, most had had little opportunity for formal education.

DESCRIPTION OF RECREATIONAL AND WORK PROGRAMS

Recreation and art therapy was provided by one full-time and one half-time therapist who visited patients referred to them by physicians, social workers, and nurses. Visits were made at intervals of from 1 to 3 weeks to teach, supervise, and encourage. On an initial visit an attempt would be made to determine what the patient's general or special interests were. Rarely a patient would be encountered who had had a leisure time pursuit or hobby in health that he was able to pursue in illness. Activities offered included: (1) painting, (2) weaving, (3) leather work, (4) ceramic tiling, (5) metal work. Most of the women also practiced traditional feminine hand skills such as embroidering, sewing, and knitting. These activities were rotated from time to time, and, in the case of patients with failing physical capacities, the character of the work was suitably modified. The emphasis in hand work was on helping the patient develop his creative ability.

The work program, Jobs for the Homebound, was in its third year during the study period. Patients worked at industrial contracts and were paid at prevailing piece rates with a minimum of 40 cents an hour. The raw materials were brought to them in their homes and the finished products picked up. The nature of the work varied, depending upon the industrial contracts which could be obtained as well as the physical capacities of individual patients. Typical contracts included: (1) assembling and packing various commercial items, (2) sewing of syringe wrappers and related hospital items, (3) addressing envelopes, (4) manufacture of tile items, (5) sorting and packaging of handkerchiefs.

In contrast to the free availability of recreational therapy, work therapy was offered only to patients who asked for work or to those suggested by the staff. It would have been clearly fruitless, and psychologically inappropriate, to have embarked on work therapy with some of our moribund cancer patients. For similar reasons patients with cerebral vascular disease, resulting in a marked intellectual deficit, were excluded. Conversely, factors that would more readily lead to a patient's being admitted to Jobs for the Homebound included relatively less disability, evidence of ambition and energy, and occasionally, background, as for example in the case of 2 with fairly severe arthritis who wished to resume their preillness occupation of sewing machine operator.

PATIENTS' RESPONSE TO RECREATIONAL AND WORK THERAPY

Of the 158 patients, 116 were offered recreation and art therapy and 29 of the 116 were also offered work. No activities were offered to the remaining 42 patients for several reasons: (1) Most of them were judged by the physician to be too sick for activity. Thus two thirds of this group fell into the severely disabled class (Group III), as compared with but one third of the total group. Approximately half of this group had cancer, as compared with 19 per cent of the

Fig. 1.—Jobs performed by Home Care patients. Reading across from left to right, lacing display card; assembly of bank bag seal; sewing hat decoration; stapling display card; envelope addressing; assembly of novelty; packaging storage bags; assembly of display card; packaging hospital dressings; assembly of bracelet; packaging handkerchiefs; block printing table mats; machine sewing of surgical glove cover; hemming and packaging towels; binding of journals: machine hemming hospital towels; manufacture of ceramic tile trivets, trays, and ashtrays.

total group. (2) Another group of patients, because of their hobbies, household duties, or social activities, were deemed capable of occupying themselves satisfactorily. (3) A small group of patients were on Home Care for relatively brief periods and were discharged before the therapist scheduled a visit.

The activity of the 116 patients with whom we had an experience of significant duration is shown in Table I.

The patients' acceptance and rejection of activity and the types of activity engaged in will be discussed in relation to sex, age, degree of disability, and diagnosis.

The Sex Factor.—Men engaged in activity somewhat more often than women.

TABLE I

ACTIVITY		NO.	%
Recreation only		45	39
Recreation and work		20	17.1
Work only		5	4.3
Activity offered and rejected		46	39.6
Patient felt too ill	20		
No interest in activities offered	14		
Satisfied with self-initiated activities	12		
Total		116	

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In our group of 70 active patients, the ratio of men to women was 43 to 57 per cent, compared with the ratio of 38 to 62 per cent for the group as a whole. The difference of course is not significant, though it must be remembered that in the absence of diversional therapy the possibilities for passing the time fruitfully at home are greater for women. This is perhaps counterbalanced by the fact that slightly more than half of the participants on the work program were men.

Although women participated less often than men, those who did participate in recreation activities did so more enthusiastically and more actively than the men. Many of the men engaged in diversional activities for very brief periods after much prodding from both therapist and family. On the other hand, the men who worked made this activity the focus of their day more frequently than did women.

The Age Factor.—There was a gradual decrease in participation in activity programs with aging, but this was less than one might have expected. Thus 54 per cent of the patients under 40 engaged in activity; 36 per cent of those between 70 and 80 did so.

An analysis of the reactions of the 55 patients over 70 gives some indication of what can be expected when activity programs are offered to a geriatric, ill population. In the over-70 group, 17 patients were not offered activity because of such illnesses as far-advanced cancer or severe cerebral vascular disease. Of the remaining 38 elderly patients, about half (20) accepted activity, and 2 of them participated in the work program.

Older patients generally took part in the activity programs on a modest scale. Of the 20 participants over 70 only 3, all women, spent a major portion of their time in activities—2 in recreation, 1 in work. The more typical pattern among the women was sewing, knitting, and crocheting, interspersed with homemaking pursuits. The men and some of the women did simple craft work such as putting together ceramic tiles, or leather and metal tooling.

In an occasional case, it was possible to bring out a high degree of creative ability which had been unsuspected. One former sea captain took up painting and produced highly imaginative canvases depicting the scenes he remembered from his travels. One elderly woman who had learned to do fine embroidery in Italy as a child took up needle work again in her 70's and wielded the needle

almost like a paint brush, embroidering brightly fanciful scenes. With others the maximum degree of creativity achieved was selecting the two colors for the weaving of a pot holder. It would appear that the amount of creative work which can be expected from most elderly people without previous experience in self-expression is limited but that there are a few who despite age and illness are capable of highly creative performance.

Only 2 of the patients over 70 worked. This was probably largely the result of bias in the selection of patients for the work program. The Home Care staff undoubtedly suggested patients on the basis of physical capacity, age, alertness, and indication of interests, so that the possibility of work was not considered for many aged and disabled patients. However, the 2 elderly patients who worked did so with great enthusiasm. One would wave his pay check around and crow, "There's life in the old boy yet." The other, a woman of 85, was nominated for the work program by her physician as a distraction to mitigate her grief following the death of her husband, also a Home Care patient. Work became the center of this woman's existence. The steady, small income she earned at machine sewing constituted a significant part of a marginal income.

Hence, while it is true that in the past-70 group there is a lower acceptance of and response to proffered activity, one must reckon on some patients with far better-than-average capacities for both creative diversional pursuits and work.

The Disability Factor.—The degree of disability, as might be expected, was an important factor governing participation in the activity programs. Of the Group I patients, the least severely disabled, 21 of 30 (70 per cent) participated. Of Group II patients, the moderately disabled, 34 of 75 (46 per cent) participated. In Group III, the most severely disabled, 15 of 53 (28 per cent) of the patients participated. In addition, the degree of participation among those accepting activity tended to deteriorate with increased disability. In all but 4 of the 15 Group III patients involved in activity, acceptance was limited; the patients engaged in activity sporadically or chiefly during the therapist's visits, with some prodding from both staff and family. The 4 severely disabled patients who became quite active had more personality resources than the others and were considered to be putting up a vigorous fight against their disability.

The Disease Factor.—The disease process per se was not as important as the degree of disability in determining acceptance of activity. However, there were interesting differences in the patterns of activity among patients in various diagnostic categories. The highest percentage of participants was found in patients with heart disease, 75 per cent of such patients taking part in activities; the poorest response was in the cancer group in which 20 per cent did so. The percentage of patients in the other categories accepting activity were: arthritis, 47 per cent; vascular diseases, 44 per cent; pulmonary diseases, 33 per cent; and miscellaneous, 64 per cent.

Heart disease and cancer: The extremes in acceptance of proffered therapy by patients are illustrated by the contrast between those with heart disease and with cancer. Since many of the patients with compensated chronic failure fall into the Group I disability classification, it is perhaps not surprising that the

highest percentage of participants was found among cardiac patients. Ten of 13 such subjects took part in activities; and, of the 3 who did not, one remained reasonably active as a housewife and another was heavily involved in the care of his home and of his wife.

The different responses to the activity programs of patients with heart disease and cancer indicated the importance not only of disability but also of emotional factors associated with a disease. The heart disease group consisted chiefly of patients who had few symptoms at rest and whose status often remained stable over periods of months and even years. Hence the desirability of diversion or work became more pressing, and the capacity for doing it remained quite predictable. On the other hand, the patients in the cancer group were our sickest patients. Some were moribund. Many had continuous discomfort of one sort or another.

Furthermore, the impact of cancer is notably different from that of the other illnesses treated on Home Care. Many cancer patients have had one or more operations and are depressed because of mutilating procedures. Cancer patients are more likely to exhibit an overt deterioration. There is also little doubt that most of these patients were not only aware of their diagnosis but had the usual depressive reactions to this knowledge. Nonetheless, note should be made that no generalizations apply to all patients. Of the 11 patients with cancer who were offered activity, 6 accepted. With them the few hours a week of diversional activity were judged to be a much-needed distraction from depressive preoccupations with tragedy.

Arthritis: With arthritis the need to keep the patient active so far as possible is now regarded as medically obligatory. All but one of the arthritic patients were women. A fair number of them were able to engage in homemaking activities. The staff strongly encouraged such activities and homemaking pursuits were in themselves often sufficient to eliminate a need for further occupation. About half (8 of 17) of those with arthritis accepted activity.

Two patients with rheumatoid arthritis participated in the work program, pursuing their preillness occupation of sewing machine operator. Both managed to work at their sewing machines as the fluctuations of the disease permitted. However, their interest in the work was spasmodic and, for one, subordinate to home and social activities, for the other, subordinate to pain.

Among the arthritic patients as among other groups, sterling exceptions were encountered. One such was a 53-year-old woman totally confined to a wheelchair for many years. She had made little effort to increase her activities of daily living. Initially she had little interest in the recreation program, but in time was prevailed upon to try painting. She revealed a significant talent which enabled her to do good paintings of the "Grandma Moses" type. Hours of each day were spent in painting, despite exacerbations of eye pain due to episcleritis.

Cerebrovascular accidents: Half of the patients with strokes (6 of 12) accepted activity. However, only 2 of the stroke patients were very active on the recreation program and none worked. The recreational activities of the 2 stroke patients who did become active were continuations of long-standing interests. One who had been a fairly skilled painter for years prior to illness learned to paint

Fig. 2,—Picture painted by Patient E. J., severely disabled with generalized rheumatoid arthritis (see text). Despite virtual immobilization of all finger motion, active arthritis of the joints of the upper extremities, and active episcleritis, the patient painted such gay landscapes as this, which obviously go back to her childhood in Sweden.

with her left hand after her stroke. The other who had worked as a potter prior to illness took up the closely related activity of ceramic tiling.

Clearly the brain damage found in some stroke patients contributed to their lack of response to proffered activity. In addition, family problems and emotional reactions to illness played an important role. Thus of the 6 stroke patients who rejected activity, 4 lived in relatively poor family situations in which the family resented giving necessary care or were not cooperative in carrying out medical procedures. Four of the 6 patients also had marked reactions to illness, either maintaining unrealistic expectations of recovery (denial of illness), or reacting with severe depression and feelings of hopelessness. Although similar problems were not absent among the 6 stroke patients who accepted activity, they seemed less intense.

Pulmonary insufficiency: Six of 14 patients with pulmonary insufficiency took part in some activity, a percentage not strikingly different from that found in most of the groups. However, those who participated did so very actively. All except one worked, and 2 undertook both recreation and work. Four of the 5 who worked were among the most productive patients on Jobs for the Homebound. Although none of them were among the sickest of the pulmonary insufficiency group—none were in Group III—all had serious dyspnea on effort.

In comparing the pulmonary patients who accepted activity with those who rejected it, we find that most of those who accepted showed a determination to tackle their life problems, an energetic attitude not prevalent among those who rejected the program. For example Mr. B. K., a 62-year-old man with chronic pulmonary emphysema, maintained a home for his two children after his wife had been confined to a mental institution. With the help of the work program, he developed his own method of bookbinding. He worked daily at his trade and earned a modest but steady supplement to a limited income. Another patient, a spirited lady of 62 with arrested pulmonary tuberculosis, pulmonary emphysema, and fibrosis, maintained a home and cared for her sister ill with cancer. She worked diligently at addressing envelopes and light assembly work and achieved her objective of building up further time under Social Security.

Miscellaneous disorders: With the other patients the degree of disability rather than the disease category was the most pertinent factor in determining acceptance of activity. Thus, of 2 patients with severe diabetes both suffering from diabetic diarrhea, recurrent infections, and peripheral neuropathy, one with severe generalized vascular disease could not be interested in activity while the other, a young man of 29 without clinically significant atherosclerosis, was an active worker. Another patient with lupus erythematosus and organic brain syndrome was content to do simple household tasks, in contrast to others without brain damage who functioned well in the recreational area. Combinations of vascular disorders such as peripheral vascular disease and aging were likely to produce disinterest in proffered activity.

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DISCUSSION

The impact of chronic disease, the variable meanings and values attached to work and recreation, and the many subtle interpersonal relations between worker and patient are all likely to produce a situation which is complex, and in which conclusions must be warily drawn. Even shifting a patient from the hospital ward to the home and turning him over to the ministrations of a new and interested team can have significant impact on the course of an illness. This we have ascribed to environmental and interpersonal factors, inasmuch as the disease process and its therapy remain basically unaltered.[6] Similar imponderable factors are not to be overlooked in the area of work and recreation therapy. Thus a recreational therapist who is personally enthusiastic over the values of painting can lead to the emergence of a respectable number of primitive painters in a homebound group. Similarly, a team worker, convinced that light industrial homework may mean psychological and physical salvation to an arthritic patient, can have a most stimulating influence on an otherwise apathetic subject. Results of this kind have perhaps been rendered the more likely because of the somewhat pioneering aspect of some phases of our Home Care Program. Despite this, our final impression is that our experiences with Home Care patients will be duplicated by others, for the significant factors do turn out to be related to such objective aspects as degree of disability, disease category, age, and the like.

As noted, the patterns of acceptance of recreational therapy were variable

and covered a full spectrum from reluctance to enthusiastic acceptance. A few patients spent some reluctant hours a week on diversional therapy out of sheer boredom and perhaps as a response to the idea that, since recreation was being offered, it should be accepted. There were some who engaged in recreational therapy by fits and starts depending on their state of well-being or on acceptance or praise from those around them. At the other extreme were some patients who engaged in recreational therapy with great energy; some flooded their households with pot holders or unleashed a torrent of hotplates, ashtrays, and fruit bowls. It was found both desirable and necessary to vary the activity engaged in, depending on the individual's output and reaction to it. Painting turned out to be perhaps the most consistently engaged in and stimulating therapy. Some patients painted steadily and with considerable self-satisfaction for many months. Even when responses were lukewarm, it was the general feeling of both recreational therapists and patients that the activities usefully broke up an otherwise long day and relieved some of the monotony of being homebound.

Perhaps because of the criteria used for selecting patients for the work program, their responses were somewhat more uniform. Generally the patients who worked showed more perseverance and more enthusiasm than did the patients who selected recreation activity. Virtually all of those who worked expressed considerable satisfaction with the idea of doing useful work and of making money. Some who had looked upon diversional therapy with only mild interest responded much more positively to work activity. A few flung themselves into work with such enthusiasm that by actual check they were found to be engaged in work for upward of 40 hours per week and collecting checks in significant amounts. Although for a limited number of patients work was a casual concern, more often work became a central activity in the patient's day, and had considerable impact on the previous life pattern. Thus one of our patients with compensated cardiac failure, a 52-year-old intelligent and moderately energetic woman, had participated only modestly in our recreation program; she engaged chiefly in sewing while she rested during the day or chatted with friends during the evening. Later, she reorganized her entire day around Jobs for the Homebound, arranging home and social activities so as to have sufficient time and physical capacity for the work. She put in a great many hours over weekends when her husband worked and always saw to it that enough materials were brought to keep her busy during such periods. Her earnings averaged $8.70 a week.

Even in the presence of marked physical limitations, work had meaningful significance. Thus a Group III patient, a young man of 21 with muscular dystrophy, had been confined to a wheelchair for years. He could use his hands only when the forearms were resting on a board. With the use of an electric stapler the patient was able to do light assembly jobs at which he worked for an hour and a half or so per day. More than this was too taxing. Despite this limited output and the moderate income from it ($4 to $5 a week), the fact that he was working for the first time in his life and able to contribute toward his upkeep was extremely meaningful. With him, work activity plus social case work were considered to be largely responsible for the lifting of a marked depression.

The glowing responses of many of our patients to work or recreation should

not lead to overlooking the fact that 40 per cent of the patients to whom our program was offered refused it. There were, in addition, the 42 patients who were adjudged to be too ill or otherwise unsuitable for our therapy. Thus, of a total of 158, there were 88 who for reasons of unsuitability or because of rejection of proffered activity never became involved in either recreational or work therapy. The 46 patients who rejected us therefore merit further examination. As noted, patients rejected activity because they felt too ill, had no interest in activities offered, or were satisfied with self-initiated activities.

Virtually all the patients who rejected the program because they were satisfied with self-initiated pursuits were women, ranging over all age groups. They were anxious to spend their available time and energy on homemaking activities. Generally, these women were adjudged not to be in particular need of activity programs, since their time was being productively occupied in pursuits normal for women at home.

Of greater concern were the patients who rejected the program because they felt themselves to be too ill and those who did so because they were not interested in the activities offered. Many of these patients had little or nothing to occupy themselves with throughout the day.

Of the 20 patients who rejected activity because they felt too ill, only 5 were actually in the severely disabled group. The other 15 patients were elderly, with a median age of 68. Almost three fourths of them were women. Many of them fell into the group with vascular disease and probably had some cerebral impairment as far as energy and initiative were concerned. In addition however to factors of age, sex, and diagnoses, two other factors appeared to be of significance. One was contentment with a limited existence, with doing less than their capacities permitted. Many performed restricted activities in the home such as a few simple household tasks. They did not have strong drives toward homemaking activities similar to those of the women who rejected activity in order to concentrate on homemaking.

The other factor was the presence of an emotional problem of some severity. Seven of the patients who felt too ill for activity had severe emotional problems. Some were depressed, others had complaints far out of proportion to the degree of their disability and were generally wrapped up in their symptoms. One was senile. One patient, C. H., was a 56-year-old woman with hypertension and arteriosclerotic heart disease. Though physically capable of managing most homemaking activities, going outside daily, and having some social life, she had virtually incarcerated herself in her apartment in the belief that she was dangerously ill. Another patient, H. K., a 77-year-old man, had chronic pulmonary emphysema and fibrosis. Though on a physical basis he was judged capable of leading a not too restricted life, his depression was of suicidal proportion. He sat forlornly at the window day after day speaking only rarely, and then only of his ill fate.

The 14 patients who rejected activity because of lack of interest were not significantly different from the group as a whole in most respects. Rejection of recreational activity was probably in part due to the character of the activities offered, the program being heavily weighted with arts, crafts, and hand skills. Although in some countries, such as Sweden and England, the practice of hand

skills is traditional for men as well as women and disabled men readily weave and even knit, American men often regard hand skills as women's work. Some of the men on Home Care expressed the desire for something useful in the way of activity and preferred, for example, repairing a broken alarm clock to the tooling of leather.

It is possible that a wider choice of recreational pursuits would have led to a higher yield of participation among the men. But even when considerable effort was made by the therapist, numerous patients were encountered who because of illness, depression, and age could not be coaxed into activity. Recognition of the existence of such a hard core should enable the therapist to abandon useless efforts without loss of self-esteem.

SUMMARY AND CONCLUSIONS

Experiences with recreational and work therapy offered to a group of chronically ill homebound patients are described. Of the 158 patients on the Home Care program in the year considered, 42 were not offered the therapy, chiefly because of severe illness. Of the remaining 116, 70 were involved in activity and 46 rejected it. Factors operating against acceptance of recreational therapy included increased disability or pain, age, and depression. Additional factors limiting extent of activity included personality resources, attitude to illness, family problems, and interest in homemaking activity.

The rate of acceptance of activity was higher among cardiac patients (75 per cent) than among others, with the lowest rate found in cancer patients (20 per cent). Men participated in the activity programs more often than women. However, the women who engaged in recreation did so more actively than the men; in contrast, the men were more active than the women on the work program. Responses to activities for diversion varied from tepid to enthusiastic with the best and most sustained response being to painting. Responses to paid work were generally more positive than to recreation, work often becoming the central activity of the day. Unsuspected capacities for both recreational and work therapy were found in outstanding individuals from all the age and illness brackets.

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A CONTROLLED INVESTIGATION OF THE CHARACTERISTICS OF ADULT PEDESTRIANS FATALLY INJURED BY MOTOR VEHICLES IN MANHATTAN

WILLIAM HADDON, JR., M.D., M.P.H.,*
PRESTON VALIEN, PH.D.,**
JAMES R. MCCARROLL, M.D.,*** AND
CHARLES J. UMBERGER, PH.D.****
ALBANY AND NEW YORK, N.Y.

From the Epidemiology Residency Program, New York State Department of Health, and the Division of Epidemiologic Research, Department of Public Health, Cornell University Medical College

(Received for publication Jan. 6, 1961)

ACCIDENTS in which pedestrians are struck by motor vehicles account for a substantial fraction of the motor vehicle accident deaths occurring in the United States. For example, in 1959, of the 37,800 persons who died as the result of motor vehicle accidents in the United States, 7,750 were pedestrians.[1] Of these, 4,850 were struck in urban areas,[1] and press reports and the scanty information available suggest that most, if not all, of the world's major cities are endemic foci of such deaths.

New York City is a major such focus, one in which approximately 70 per cent (1955-1959) of those killed in motor vehicle accidents are pedestrians. In 1959 deaths of pedestrians accounted for 515 of the 737 killed as the result of accidents in the five boroughs of the city, and an unknown additional number occurred in the extensive surrounding urban area. During the same period, pedestrian deaths in New York City constituted 6.6 per cent of the pedestrian deaths in the nation and 62 per cent of those in New York State.

Despite the long history of this problem and its present magnitude, relatively little is known as to the characteristics of those killed, particularly in comparison with the characteristics of those who though similarly exposed are nonetheless not similarly involved. Although it has been known for many years that a large

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The preliminary report of this work was read at the Panel Discussion on Epidemiology of Trauma, New England Sectional Meeting, American College of Surgeons, Boston, Feb. 29, 1960.

This investigation was supported, in part, by the New York State Departments of Health and Motor Vehicles, and by a research grant (RG-5937) from the Division of Research Grants, United States Public Health Service.

*Director, Epidemiology Residency Program. Formerly Director, Driver Research Center, New York State Department of Health—State Department of Motor Vehicles.

**Formerly, Associate Director, Driver Research Center.

***Director, Division of Epidemiologic Research, Department of Public Health, Cornell University Medical College.

****Chief Toxicologist, Office of the Chief Medical Examiner, New York City.

percentage of such fatally injured persons have been drinking heavily,[2,3,4] heretofore no one has determined the extent to which the population similarly at risk has been drinking. It has also been long known that the age-specific fatality rate distribution of those killed throughout the United States is J-shaped with a maximum in the grade school and preschool years and a minimum in the 15 to 34 year range, followed by large, progressive increases in the subsequent decades.[1,5,6] Again, however, it has not been known whether or not the age distribution of those similarly exposed is the same, or whether the age distribution of those killed results in part from an age-associated risk.

Despite this lack of scientifically gathered information large sums are spent annually throughout the United States in "pedestrian control" programs, public exhortations, and other measures which though often reasonable have not been the subject of adequately designed evaluations. To the contrary, much has been made of short-term fluctuations in incidence, both as evidence of the efficacy of such measures where the changes have been downward and, where the reverse has been the case, as evidence for their need.

The investigation described in this report emphasized the characteristics of accident-involved and non-accident-involved pedestrians rather than the characteristics of involved drivers and accident sites, although these are also undoubtedly of importance. The pedestrian characteristics chosen for study included age, sex, blood alcohol concentration, socioeconomic status, and others believed to be of more fundamental importance than the "pedestrian actions" (for example, disobeying given traffic regulations) around which most discussion of pedestrian accidents is centered. Since it was decided to study the pedestrian accident problem in adults rather than that in children, where somewhat different factors would be expected to be of importance, an "adult pedestrian" was defined for the purposes of this study as any pedestrian 18 years of age or older, a cutoff point which falls in the 15 to 34 years of age minimum in the fatality rate distribution. For practical reasons the investigation was limited to Manhattan.

METHODS

Case Series.—With the exceptions to be noted, the case series consisted of 50 of the 52 pedestrians 18 years of age and older who died *as the result*, confirmed by autopsy and the weighing of the total of available information, of being struck by motor vehicles at known Manhattan sites and times between May 3 and Nov. 7, 1959, and whose deaths occurred during the same period. The 52 deaths consisted of all such deaths known to the Accident Investigation Squad of the New York City Police Department and the Office of the Chief Medical Examiner. The 2 omitted cases were deleted through clerical errors.*

*A number of borderline cases were omitted as not meeting the above criteria. Included in this borderline group were: (1) two cases in which pedestrians, both elderly, died as the result of being hit by bicycles; (2) one case of homicide in which the pedestrian was pushed into the path of an oncoming car; (3) one case in which an injured 72-year-old woman who had stated that she had been knocked down by a car died without revealing the site or time of her accident; and (4) one case in which an 81-year-old man convalescing from a fractured pelvis and other injuries sustained when hit by an automobile died of coronary occlusion confirmed at postmortem examination by the finding of a fresh coronary thrombus.

Postmortem examinations were performed in all cases, almost invariably on the morning following death. Whenever possible, blood from the heart or superior vena cava was obtained in cases in which survival had not exceeded 6 hours. Specimens of brain were also usually obtained. Since all of these specimens were negative for reducing substances other than ethanol[7] they were next analyzed with the use of a modified Widmark method.[8] The results were reported in milligrams of ethanol per 100 grams of specimen (milligrams per cent by weight), and each such analytical result was rounded off to the nearest 10 mg. per cent.

Data relative to the characteristics of the deceased and the circumstances of the accidents were obtained from the records of the Accident Investigation Squad, from the Office of the Chief Medical Examiner, and, in the case of motor vehicle operators' licenses, from the records of the New York State Bureau of Motor Vehicles. Additional data with respect to weather were obtained from the hourly observations of the New York Meteorological Observatory, Central Park.[9]

Control Group.—In brief, a control group was obtained by: (1) visiting each accident site on a *subsequent* date, but on the same day of the week and at a time as close as possible to the exact time of day of the accident; and (2) interviewing and obtaining breath specimens for alcohol analysis from the first 4 adult pedestrians of the same sex as the deceased reaching the site (see below). This resulted in a control or comparison group of 200 individuals comprising a sample of the universe defined by matching in each index case for sex, exact accident site, and time of day and day of week of accident.

As each death occurred, the case was added to the roster of cases for which controls were to be obtained during the next sampling period. These sampling periods were scheduled weeks in advance to fall at approximately 4 week intervals. Tuesdays and Wednesdays were treated as one day when convenient for scheduling purposes, but the 4 member control group for only one case of the 12 which had occurred on Tuesdays or Wednesdays was obtained on a different day from the day of week of accident occurrence. With this single exception, 48 of the 49 sites (one accident had resulted in 2 deaths) were visited on the same day of the week as that on which the accident had occurred. Under this sampling period procedure, 28 sites were visited within 4 weeks (i.e., $\leq$ 4 weeks) after the corresponding accidents, 38 within 5 weeks, and all but 8 within 6 weeks.

Two of the case accidents occurred on legal holidays, and 2 of the site visits also fell on legal holidays. As a result, no appreciable biases due to the inclusion or exclusion of such days are believed to have been present.

The site visits were made by a team of two or three of the authors and one to four medical students working at each location with one or two uniformed members of the Police Department Accident Investigation Squad (A.I.S.).

In visiting each site one of three basic approaches was used. In the first type, that used in many busy neighborhoods, for example, opposite Grand Central Station on a weekday at 6:10 P.M., the entire team arrived and immediately stopped the *first* 4 adult pedestrians of the same sex as the deceased. At such busy sites the group arrived and accomplished its purposes in 5 minutes or less from start to finish.

When the accident site was in a neighborhood in which it was suspected that the group might be seen and avoided, a second approach was used. Under such circumstances, for example, at sites in the Bowery, the group arrived and "swept the block" stopping successively the *first* 4 adult pedestrians of the required sex who were headed toward or away from the accident site. By pedestrian here and throughout this report is meant a person progressing by walking, not lounging stationary, sitting, or lying down.

In the third approach, used where pedestrian traffic was very light, for example at 108th Street and the East River (F.D.R.) Drive at 1:40 A.M., the group would lounge nearby or sit in a car at or near the site watching for approaching pedestrians, and as each of the *first* 4 of these came into view he, or, where appropriate, she, was quickly approached and stopped.

The site visited was the sidewalk point closest to the exact location of the accident as described on the police or medical examiner's report. For example, one report indicated that the deceased had been crossing the street 40 feet from a given corner. This was found to be directly in front of a "rathskeller," and it was at that point that the first 4 pedestrians were stopped.

Great care was taken to avoid any attempt at matching for the characteristics of the deceased, except in so far as sex and adulthood were concerned. In addition, for methodologic uniformity, at all sites the same investigator pointed out to the accompanying police each individual to be stopped. Although the exact details varied with the circumstances, the person was immediately approached and told by the policeman, "Please step over for a minute while the *doctors* ask you a few questions." A nearby member of the team immediately stepped up and began talking uninterruptedly: "I don't want to know your name; I merely want to ask you a few questions. Do you live in Manhattan?" The interview was usually easily begun in this manner, although 12 refusals occurred (see below).

To obtain the 4 pedestrians comprising the sample at each site, *all* pedestrians of the appropriate sex who appeared to be in their mid-teens or older were stopped until the requisite number of persons was obtained. Mid-teenagers were stopped in this manner to avoid biases which might otherwise have been introduced had the decision as to whether or not given individuals were or were not 18 or over been left to the investigator who was pointing out the persons to be stopped. In such borderline cases the interviewee was first asked his or her age, and if it fell below 18 the next pedestrian of the same sex was immediately stopped.

Where the individual stopped refused to cooperate, the pedestrian who followed immediately was stopped. For the purposes of this report a "refusal" is considered any case in which the individual met the sampling criteria, but from whom it was impossible to obtain *both* the complete interview *and* the breath specimen. Under this definition, there were *no* refusals at 39 of the 49 sites. There was one refusal at each of 10 sites, and at one site there were 2 refusals.

This investigation was carried out without publicity of any kind. With one exception it was invariably possible to stop the members of each pedestrian sample prior to the formation of the substantial group of watchers which sometimes formed thereafter. The exception, in a "tough" neighborhood at 2:30 A.M.,

involved the only site at which 2 persons had been fatally injured in the same accident. On arrival, it was possible to obtain quickly the first 7 but not the eighth interview and specimen of breath, a small, hostile crowd quickly forming from an adjacent bar. As a result, only the first 4 of the 7 interviews and specimens obtained at this site were used, being counted twice in the analyses of the data.

The interview included questions as to: place and length of residence; place of birth; age; present occupation; and marital status. Sex, apparent race, appearance and apparent sobriety, date, location, time of interview, and weather were also recorded.

Immediately on finishing the interview the interviewer stated approximately as follows, "I only have one more thing for you to do (and then you can go) and that is to blow up this bag for me." Simultaneously he removed a Saran bag (see below) from an envelope and showed the pedestrian how to place one of its two ends in this mouth and blow until told to stop. This finished, the pedestrian was thanked and told that the interview was over.

A large percentage of those interviewed were foreign born, and many of these admitted to no knowledge of English. Rather than weaken the investigation by omitting these pedestrians when no member of the team knew a common language, passersby were stopped and asked to serve as interpreters. Apparently because those walking in the same neighborhoods or, in some cases, accompanying those stopped (many of the latter being interviewed themselves) tended to know the same languages, this procedure proved very satisfactory. With its use no one failed to be interviewed because of a language barrier and interviews were completed in Armenian, German, Greek, Spanish, and other languages and dialects.

The average interview was recorded as beginning 1.5 minutes after the recorded time of the corresponding accident. One hundred and fifty-nine of the 200 paired time differences were within plus or minus 15 minutes (i.e., $\leq$ 15 minutes), and 179 were within 20 minutes. All interviews were obtained within 55 minutes of the corresponding accident times, and in only 7 instances did the difference exceed 30 minutes. These rare, longer intervals were considered preferable to obtaining variable numbers of controls at each site, a procedure which would have biased the control group toward the characteristics of the pedestrians at sites at which controls were more quickly obtainable.

Breath Specimens.—The Saran bag employed for the collection of the breath specimens was recently developed in the Department of Pharmacology, University of Toronto, for the collection of breath specimens from drivers suspected of drunken driving.[10] It represents a substantial methodologic advance since alcohol-containing breath specimens collected in it show only negligible losses in alcohol *concentration* with prolonged holding. This is in marked contrast with that obtained with other collection devices.[11] For example, the concentration of alcohol in rubber balloons falls by about one half in 15 minutes.[11] Alcohol-containing breath specimens collected in this manner prior to the transfer to the analytical apparatus (below) give results which are not significantly different from those obtained when the specimen is collected directly in that apparatus.[12]

The breath specimens were invariably analyzed within approximately 2

to 3 hours of collection. On returning to the laboratory, the breath-containing bags were placed for approximately one quarter hour or more in an incubator at approximately 40°C. in order to evaporate the condensate which had meanwhile formed inside, a precaution taken to avoid the possibility that changes in alcohol concentration in the gaseous phase might occur as the result of alcohol's differential solubility in the aqueous condensate. On removal from the incubator each specimen was very quickly transferred to the "Breathalyzer." The Breathalyzer is a commercially produced photoelectric device which, under standardized conditions, compares 2 ampules of potassium dichromate–sulfuric acid solution through one of which the breath specimen has been bubbled.[13] This results in an estimate, expressed to the nearest 0.01 per cent by weight (10 mg. per cent by weight), of the blood alcohol concentration at the time the breath specimen was collected. The reliability and accuracy of this device, when properly used, in estimating blood alcohol concentrations has been repeatedly documented.[13,14]

The Saran bags and the Breathalyzer subsequently used were not yet available at the time at which the site visits for the first 5 cases were made, and the 20 controls for these cases have been listed in the data as "no alcohol controls." However, at these sites breath specimens were collected, usually in toy balloons, as a part of the interviewing procedure, which was otherwise unchanged.

Cases Employed for Alcohol Comparisons.—Because of the relatively rapid rate at which alcohol is metabolized, the longer the interval between accident and death in any case, the greater was the probable postaccident lowering of the blood alcohol concentration.[15,16] Consequently, as a compromise between the necessity of having as large a case group as possible for the alcohol comparisons and the need to work with a group in which as little metabolic lowering as possible had occurred, only cases in which survival was less than 6 hours were used for such comparisons, with the exception that the 2 such short-survival cases among the first 5 cases referred to above were also not included in these comparisons since comparable controls were not obtained. To the extent to which such lowering occurred, this diminished the actual differences in this respect between the cases and the controls. In order to gain information as to the blood alcohol concentrations of those in the *total* control group, in addition to that portion of it derived from sites involving less than 6 hour survivals, specimens for analysis with the Breathalyzer were obtained from all of those successfully interviewed at all but the first 5 accident sites.

Comment on Methodology.—The obtaining of the accident site–matched controls on *subsequent* dates, rather than immediately following each accident, obviates three practical difficulties present when immediate site visits are attempted. First, it may be hours, days, or weeks before it is known whether or not a given case meets the criteria for admission to the series under study. Second, even when a decision to visit a site can be made immediately on notification of each successive accident's occurrence (and this requires that personnel be continuously on call), the time lags inherent in notification and travel to the site result in the controls always being obtained substantially later than the times of occurrence of the corresponding accidents. Third, since groups of onlookers often form immediately and remain for some time at such sites immediate sampling

would probably result in sampling biases. These difficulties are not encountered with the experimental design employed in this investigation.

Such subsequent sampling, however, raises the possibility of pertinent intervening changes in the characteristics of pedestrians at the site. Changes of this type are believed greatly minimized by the matching for day of week, exact time of occurrence, sex, and adulthood, and these matchings were very successfully achieved. In addition, the weather (raining, or not raining) at 39 of the sites *at the times the interviews were obtained* (see below) was the same as at the times of the corresponding accidents, and it is likely that at least at these 39 sites the pedestrian and traffic *densities* were comparable to those at the times of the corresponding accidents. Also, the average accident site visit interval was quite short, less than 4 weeks, and the average temperature difference between the daily means for the accident dates and those of the visits was only −4°F. Finally (see footnote, Table V), it was established that there were no statistically significant shifts with time of year in the mean age of the fatally injured or in the mean age of the site-matched controls. These and the foregoing considerations lend additional confidence to the sampling method employed.

The fact that only 212 persons meeting the sampling criteria had to be stopped to obtain the 200 site-matched controls makes it very unlikely that any appreciable biases from this source were present. The majority of these 6 males and 6 females who refused were sober, well dressed, and often hurrying pedestrians. Six gave full interviews, 2 answered some questions, and 4 none. Three are known to have been drinking, 2 heavily, one of the latter being too intoxicated to blow up a bag. On the basis of the available evidence it is very unlikely that the exclusion of this small group resulted in any substantial biases.

Finally, it is pertinent that one previous investigation which found among accident-involved *drivers* a large, statistically significant excess of persons who had been drinking heavily used a somewhat similar design. In it "a year round checking of the breath of some accident and non-accident . . . operators in . . . Toronto . . . was made." "Each week from Monday until Saturday, 6:30—10.30 P.M. or later, . . . police accompanied by a research worker . . . attended as many traffic accidents . . . as possible. For each driver involved in an accident four or more non-accident drivers passing the scene . . . in cars of the same vintage at approximately the same time provided breath samples . . . ."[17] It was not known whether or not this method of study gave a representative sample of the universes of all accident and non-accident involved drivers.[18] However, this investigation, in which breath specimens were obtained from 2,015 *drivers*,[17] and that reported by Holcomb in which breath specimens were collected from 1,750 *drivers* passing certain traffic sampling points in Evanston, Illinois,[17,19] suggested the possible feasibility of the Manhattan pedestrian accident investigation reported here.

RESULTS

Fig. 1 shows the accident sites. Tables I and II give the day of week and time of day of occurrence, and Table III the distribution of the 50 postaccident survival intervals.

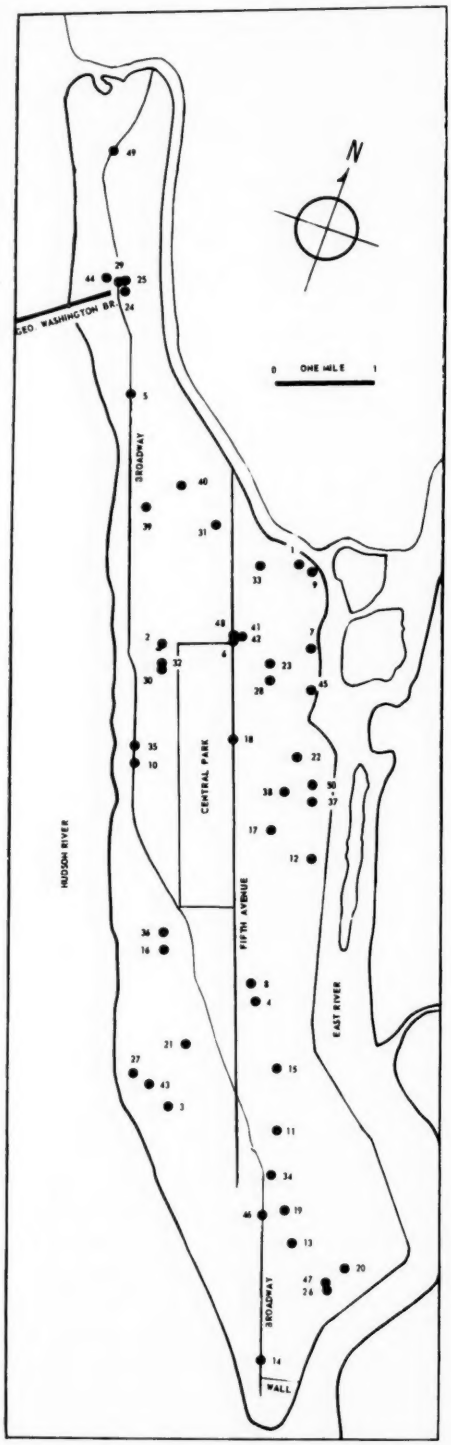

Fig. 1.—Locations at which 50 adult pedestrians were fatally injured, Manhattan, May-November, 1959.

The location numbers indicate the sequence of occurrence. The 12 females in the series were fatally injured at sites 2, 9, 10, 12, 22, 25, 30, 31, 32, 35, 44, and 49. Over longer periods than that studied there is a marked concentration of deaths in the Bowery area (sites 13, 19).

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TABLE I. DAY OF WEEK OF ACCIDENT

	SUN.	MON.	TUES.	WED.	THURS.	FRI.	SAT.	TOTAL
No. of accidents	5	6	4	8	8	8	10*	49*

*Includes one accident in which 2 persons were fatally injured.

TABLE II. TIME OF DAY OF ACCIDENT

	A.M.				P.M.				
	12-2	3-5	6-8	9-11	12-2	3-5	6-8	9-11	TOTAL
No. of accidents	6*	3	2	3	5	5	11	14	49*

*Includes one accident in which 2 persons were fatally injured.

TABLE III. POSTACCIDENT SURVIVAL OF 50 ADULT PEDESTRIANS FATALLY INJURED BY MOTOR VEHICLES, MANHATTAN, MAY-NOVEMBER, 1959

LENGTH OF SURVIVAL	NO. OF CASES
< 1 hour and dead on arrival	13
1 < 2 hours	3
2 < 3 hours	4
3 < 4 hours	1
4 < 5 hours	—
5 < 6 hours	1
6–11 hours	1
12–23 hours	5
1 day	5
2 days	1
3 days	2
4 days	3
5– 7 days	5
8–14 days	4
15–30 days	—
> 30 days	2
Total	50

Table IV compares the weather (raining or not raining) at the accidents with the weather at the site visits. In making this comparison, the table gives first the weather at the time each site visit was first scheduled and includes the weather as found on first visit to the 4 sites which had to be revisited because on first arrival it was found that the police were absent because of higher priorities elsewhere. The last column includes the weather at these 4 sites at the time of the second, completed visits.

The experimental design was based upon obtaining site-, time-, and sex-matched controls for persons *fatally* injured. On this basis alone it would have been impossible to differentiate between age-associated accident involvement

TABLE IV. WEATHER AT ACCIDENTS AND AT SUBSEQUENT SITE VISITS

	NO. OF ACCIDENTS	SITE VISIT AS FIRST SCHEDULED*	SITE VISIT AS COMPLETED*
Raining	13†	7†	8
Not raining	37	43	42
Total	50	50	50

*See text.
†Probability of observing this difference (13/50 vs. 7/50) by chance: P = 0.13.

risks and age-associated risks of death, granted accident involvement.* Since it was considered quite possible that older persons had both higher risks of being hit than younger persons similarly exposed, *and* higher risks of death once hit, additional data as to the age of pedestrians involved in nonfatal motor vehicle accidents were obtained. This information was not available at the time the investigation was begun in May, but beginning October 1 the age and sex distributions of all pedestrians known to the police as injured but not killed in accidents in Manhattan became available. Table V summarizes these data in comparison with those obtained from the case series and the site-matched controls.

Because several of the characteristics of the cases and controls would be expected to be age-associated, where appropriate, each of the tables which follows gives both comparisons between the corresponding characteristic in the case group and in the total control group, and similar comparisons between the case group and an age-matched control group derived from the total site-matched control group. This matching was performed by matching each case with the one member of the control group of the same sex most nearly of the same age, and not more than 4 years different in age. Where more than one choice was possible a table of random digits was used to make the choice. It was thus possible to match 43 of the 50 cases, and these constitute the basis of the age-matched comparisons given in Tables VI, VII, IX, X, and XI.

Tables VI, VII, and IX, respectively, give the comparisons for place of birth, place of residence, and marital status. Table VIII gives the distribution of distances between individuals' exact residences and their accident sites, and Table X gives the data with respect to socioeconomic status as judged by occupation.[2]

It is recalled that because of the rapidity of the metabolism of ethanol only those persons surviving less than 6 hours (and not among the first 5 cases, see above) are considered from the standpoint of their postmortem blood alcohol concentrations. Table XI*A* compares the alcohol concentrations of such persons with those in the *entire* control group (omitting the 20 controls for the first 5 cases). Table XI*B* compares the alcohol concentrations of the same individuals

*Accident causation research and statistics involving groups defined by given severities of injury have very consistently overlooked the possibility of pertinent associations between age and susceptibility to injury per se, as shown here and subsequently an important point. As a result such data are often of very limited value.

TABLE V. AVERAGE AGE OF FATALLY INJURED PEDESTRIANS, SITE-MATCHED PEDESTRIAN CONTROLS, AND NONFATALLY INJURED PEDESTRIANS

	FATALLY INJURED	SITE-MATCHED CONTROLS	NONFATALLY INJURED*
Mean age total†	58.8	41.6	48.4
Males	59.2‡	40.9‡	47.4‡
Females	61.7‡	43.7‡	50.3‡

*The injured-group means were derived from police records summarizing the age and sex distributions of the 209 pedestrians 18 years of age and over known to the police as having been nonfatally injured in Manhattan in the three periods: Oct. 1-7, Nov. 1-7, and Dec. 1-7, 1959. It is noted that the last 2 site visits fell on December 12.

†Because of the possibility of associations between time of year and age, the age distribution of the 18 cases and 104 controls entering their series on October 1 or later were tested for significance in comparison with the total case and control groups, respectively. Since neither of these showed significant differences (P = 0.28 and 0.52, respectively), the significance of the differences between the mean ages of the total members of each of the three groups were next tested and found highly significant (see text).

‡Since the mean ages of the males and females in each column were found to be not significantly different, the comparisons between the three groups were based upon the mean ages of the total individuals of both sexes in each group.

TABLE VI. PLACE OF BIRTH

	*A**				*B*†			
	CASES		SITE-MATCHED CONTROLS		AGE AND SEX-MATCHED CASES		AGE AND SEX-MATCHED CONTROLS	
	NO.	%	NO.	%	NO.	%	NO.	%
Continental United States	15	30.0	113	56.5	15	34.9	21	48.8
Outside Continental United States	26	52.0	87	43.5	21	48.8	22	51.2
Unknown	9	18.0	—	0.0	7	16.3	—	0.0
Total	50		200		43		43	

*In *A*, P = 0.02 (χ^2 omitting unknown).
†In *B*, P = 0.52.

with those of the controls obtained at the same accident sites, and Table XI*C* compares the 17 such persons with less than 6 hour survival included in the 43 cases successfully matched for age and sex with the members of the control group with which they were matched.

DISCUSSION

The design and methods employed in this investigation represent the development of a theoretically and practically clean and efficient approach to the controlled study of certain aspects of accident phenomena. Although only a small number of the details of design and methodology are new, taken together they represent a unique contribution. Their application, in addition, has resulted in one of the very few well-controlled accident investigations completed to date.

TABLE VII. PLACE OF RESIDENCE

	A*				B†			
	CASES		SITE-MATCHED CONTROLS		AGE AND SEX-MATCHED CASES		AGE AND SEX-MATCHED CONTROLS	
	NO.	%	NO.	%	NO.	%	NO.	%
Manhattan	42	84.0	142	71.0	35	81.4	31	72.1
Other New York City	2	4.0	30	15.0	2	4.7	5	11.6
Other New York State	2	4.0	9	4.5	2	4.7	4	9.3
Other	—	0.0	19	9.5	—	0.0	3	7.0
Unknown	4	8.0	—	0.0	4	9.3	—	0.0
Total	50		200		43		43	

*In *A*, P = 0.004 (χ^2, Manhattan vs. total of other, unknown omitted).
†In *B*, P = 0.04.

TABLE VIII. DISTANCE BETWEEN PLACE OF RESIDENCE AND SITE OF FATAL ACCIDENT*

DISTANCE	NO.
0– 499 feet	12
500– 999 feet	9
1,000–1,499 feet	3
1,500–1,999 feet	3
2,000–2,499 feet	5
2,500–3,499 feet	4
3,500–1 mile	2
1–2 miles	1
2–3 miles	2
3–8 miles	0
8–9 miles	1
Unknown	4
Nonresident	4
Total	50

*These data were obtained by locating each accident site and the residence of the corresponding fatally injured person as precisely as possible on a large map of Manhattan and measuring their straight line separation.

The accidents studied tended to occur, as previously reported for other cities,[21] outside of the major business and shopping areas (Fig. 1). They fell predominantly in the evening, late evening, and very early morning hours (Table II), as often previously reported. Seventy-three per cent (36/49) of the accidents occurred in the 12 hour period beginning at 3 P.M., and 51 per cent (25/49) in the 6 hours immediately preceding midnight. In the 3 hour period ending at 9 A.M., a period when the city's motor vehicle and pedestrian traffic increases sharply, only 2 such fatal accidents occurred, the smallest number in any 3 hour period. This, by itself, should suggest that gross exposure per se is not the major de-

TABLE IX. MARITAL STATUS

	*A**				*B*†			
	CASES		SITE-MATCHED CONTROLS		AGE AND SEX-MATCHED CASES		AGE AND SEX-MATCHED CONTROLS	
	NO.	%	NO.	%	NO.	%	NO.	%
Married	15	30.0	114‡	57.0	14	32.6	25§	58.1
Widowed	10	20.0	15	7.5	9	20.9	6	14.0
Divorced	2	4.0	11	5.5	2	4.7	3	7.0
Never married (single)	14	28.0	60	30.0	12	27.9	9	20.9
Unknown	9	18.0	—	0.0	6	14.0	—	0.0
Total	50		200		43		43	

*In *A*, P = 0.01 (χ^2 combining widowed and divorced and omitting unknown).
†In *B*, P = 0.19.
‡Includes 8 "separated."
§Includes one "separated."

TABLE X. SOCIOECONOMIC STATUS

	*A**				*B*†			
	CASES		SITE-MATCHED CONTROLS		AGE AND SEX-MATCHED CASES		AGE AND SEX-MATCHED CONTROLS	
	NO.	%	NO.	%	NO.	%	NO.	%
Upper third‡	7	14.0	59	29.5	5	11.6	11	25.6
Middle third§	12	24.0	74	37.0	12	27.9	15	34.9
Lower third‖	18	36.0	37	18.5	16	37.2	8	18.6
Housewives and unknowns	13	26.0	30	15.0	10	23.3	9	20.9
Total	50		200		43		43	

*In *A* P = 0.003 (χ^2 omitting housewives and unknowns).
†In *B*, P = 0.07.
‡000–399 in U.S. Bureau of Census classification of occupations.
§400–699.
‖700–999.

terminant of the occurrence of such accidents, and that the factors of importance are more active at other times of day. These findings are consistent with what might be expected in view of the overrepresentation in the case group (see below) of the elderly, of persons with high blood alcohol concentrations, and of Manhattan residents.

The predominantly evening and nighttime occurrence of these adult pedestrian accidents (Table II) and the frequently short survival (Table III) under-

TABLE XI *A*. BLOOD ALCOHOL CONCENTRATIONS

BLOOD ALCOHOL CONCENTRATION	SURVIVING LESS THAN 6 HOURS*		TOTAL SITE-MATCHED CONTROLS†		
	NO.	%	NO.	%	
00 (none)	5	25.0	118	65.6	Employing partial χ^2, $P < 0.10$, > 0.05, comparing the 00 and 10-40 groups in the case and control groups. $P > 0.20$, comparing similarly the number in the 00-40 and 50-140 groups. $P < 0.001$, comparing the 00-140 and 150+ groups. The total χ^2 yielded $P < 0.001$.
10–40	5	25.0	30	16.7	
50–90	1	5.0	14	7.8	
100–140	2	10.0	5	2.8	
150–190	5	25.0	3	1.7	
200–240	1	5.0	6	3.3	
250–290	—	0.0	1	0.6	
Laboratory loss	1	5.0	3	1.7	
Total	20‡		180		

*Includes all of the less than 6 hour survival cases except for the 2 among the first 5 cases. See text. The 00, 50-90, and 100-140 groups each contain one value based upon analysis of brain rather than blood. It is noted that brain alcohol concentrations tend to be lower than the corresponding blood concentrations.[15]

†No alcohol controls were obtained from Cases 1-5. See text.

‡Of the 20 persons who died within 6 hours 7 were women, 3 of whom were in the 00 group. Three were in the 10-140 group and one was in the 150-190 group.

TABLE XI *B*. BLOOD ALCOHOL CONCENTRATIONS

BLOOD ALCOHOL CONCENTRATION	SURVIVING LESS THAN 6 HOURS		SITE-MATCHED CONTROLS FROM SAME SITES		
	NO.	%	NO.	%	
00 (none)	5	26.3	55	72.4	Employing partial χ^2, $P < 0.02$, comparing the numbers in the 00 and 10-40 groups in the case and control groups. $P > 0.20$, comparing similarly the numbers in the 00-40 and 50-140 groups. $P < 0.001$, comparing the 00-140 and 150+ groups. The total χ^2 yielded $P < 0.001$.
10–40	5	26.3	8	10.5	
50–90	1	5.3	7	9.2	
100–140	2	10.5	1	1.3	
150–190	5	26.3	—	0.0	
200–240	1	5.3	3	3.9	
250–290	—	0.0	1	1.3	
Laboratory loss	*	0.0	1	1.3	
Total	19		76		

*One case in which laboratory-lost specimen is omitted, as are its 4 site-matched controls (all of which were in the 00 group).

score the need for emphasizing the evening, nighttime, and early morning in the organization of emergency medical care, a point of general relevance in the motor vehicle accident picture. It is well known, for example, that the majority of other types of fatal motor vehicle accidents also tend to occur at such times of day,[1,22] and that rapid death is common.[22]

Table IV shows that weather (raining vs. not raining) was *not* significantly

TABLE XI *C.* BLOOD ALCOHOL CONCENTRATIONS

BLOOD ALCOHOL CONCENTRATION	AGE AND SEX-MATCHED CASES WITH LESS THAN 6 HOURS' SURVIVAL		CORRESPONDING AGE AND SEX-MATCHED CONTROLS		
	NO.	%	NO.	%	
00 (none)	3	17.6	13	76.5	Because of the small numbers here, the data were combined into concentrations: (1) less than 50 mg. %, and (2) 50 mg. % and higher. P = 0.02 (exact test).
10–40	5	29.4	1	5.9	
50–90	1	5.9	1	5.9	
100–140	2	11.8	1	5.9	
150–190	5	29.4	—	0.0	
200–240	1	5.9	—	0.0	
Laboratory loss	—	0.0	1	5.9	
Total	17		17		

associated with the occurrence of the accidents studied. However, since pedestrian *density* may be lower in the rain, the risk per unit of exposure *may* nonetheless be higher in the rain than in its absence, a point outside of the experimental design employed.

One of the most striking findings is that those killed averaged some 17 years older than whose who though similarly exposed were not similarly involved (Table V), a very highly significant difference ($P < 0.001$). As noted previously, without additional information it would not have been possible to determine whether this difference was the result of: (1) greater risk of accident involvement with age; (2) greater susceptibility to fatal injury once involved; or (3) a combination of both. With the use of the additional data relative to the injured, it was found that the mean age of the nonfatally injured was intermediate between the mean age of those killed and the mean age of those similarly exposed at the fatal accident sites. Each of these differences (viz., fatally injured vs. site-matched controls; fatally injured vs. nonfatally injured; and site-matched controls vs. nonfatally injured) was also very highly significant ($P < 0.001$). The most reasonable interpretation is that there is an increased risk of accident involvement with increased age, and that in addition there is with age an increased risk of fatal outcome, once involved. The former has often been suggested, but not previously documented; the latter is consistent with much clinical evidence relative to shifts with age in the results of trauma. Both indicate that the pedestrian's chances of surviving his mechanized environment decrease with increased age.* Many factors, however, other than age are undoubtedly of im-

*Haddon and McFarland, in discussing (1958) knowledge of the physical thresholds of human head injury and the importance of such information for the purposes of automotive crash design, emphasized that there appeared to be no threshold data available with regard to either the young or the old. They stated further: "In view of the marked anatomic differences such as the open fontanelles exhibited by infants and the differences in proportion, structure and mass shown by the immature, one would expect discontinuities or at least changes in thresholds during the first two decades. Similarly, the clinically common changes with age, including alterations in tissue elasticity, bone density, superficial soft tissues, and cerebral blood supply seen in those passing middle age suggest that these groups also undergo shifts, probably downward, in their abilities to successfully resist abrupt changes in velocity . . . ."[23] The present results are consistent with the latter expectation.

portance in individual cases, as is suggested by the fact that the youngest of those fatally injured was in his twenties, that 6 were in their thirties, and that 8 were in their forties.

Tables VI, IX, and X show that those fatally involved were, in comparison with those not involved, significantly more often foreign born, less often married, and more often of lower socioeconomic status. However, none of these differences remained significant when the older age of the persons was taken into account (Tables VI, IX, and X). Neither Negroes nor persons born in Puerto Rico, two major Manhattan population groups, were found significantly more or less often in the case group than among the controls, and no geographically definable foreign-born group was significantly overrepresented in the data summarized in Table VI.

Table VII shows: (1) that visitors and commuters were not to any substantial extent represented in the case group; and (2) that Manhattan residents were significantly more often found in the case group than in the control group, even when the older age of the former was taken into consideration. It is of interest in this context that many of those killed were hit very close to their residences (Table VIII). This cannot be attributed entirely to a corresponding localization of exposure since, as just noted, Manhattan residents had a higher risk than nonresidents similarly exposed *at the same sites.*

Table XI shows that the presence of ethyl alcohol in the blood, particularly in high concentration, was highly associated with such accident involvement, that only a minority of those killed who died within 6 hours had not been drinking, and that the findings were similar whether the comparison was made with the total control group, with the controls from the same sites, or with the age- and sex-matched controls. These findings are similar to and consistent with those relative to *drivers* obtained by other workers using laboratory, field trial, and epidemiologic methods.[16,17,24-28]

The smallness of the series precludes the estimation of relative risk as a function of blood alcohol concentration, but it is seen (Table XI *B*) that persons with blood alcohol concentrations in the low, 10-40 mg. per cent range (0.01-0.04 per cent by weight) were found significantly ($P < 0.02$) more often among the cases than among the noninvolved controls obtained from the same accident sites. Although the disproportion is seen to become much greater at the higher alcohol concentrations, it is pertinent that Smith and Popham,[25] on the basis of a comparison of accident-involved *driver's* blood alcohol concentrations in relation to their estimated responsibilities for their accidents, found that accident-responsible drivers were statistically first overrepresented in the 30 to 50 mg. per cent blood alcohol range. Similarly, a number of very well-designed laboratory and field studies have shown that some *drivers* with concentrations below 50 mg. per cent show decreases in pertinent skilled performance directly attributable to the pharmacologic effects of ethyl alcohol.[16,24,26-28] The present findings suggest that the ability of at least some *pedestrians* to negotiate city traffic without fatal mishap begins to deteriorate significantly in the 10-40 mg. per cent blood alcohol range, although other factors associated with the use of alcoholic beverages might also contribute.

To place these concentrations in perspective, on the basis of competent research, it has been demonstrated, for example, that a 155 pound man drinking in one hour or less and one to two hours after an average meal would probably reach a blood alcohol concentration of 50 mg. per cent by consuming a minimum of approximately 5 ounces of U.S. 80 proof liquor,* a concentration of 100 mg. per cent by consuming a minimum of approximately 7½ ounces, and a concentration of 150 mg. per cent by consuming a minimum of approximately 10 ounces, all under the same conditions.[16] In the *case* series the percentages of those killed whose blood alcohol concentrations were at or above these three values were 47 per cent (9/19), 42 per cent (8/19) and 32 per cent (6/19), respectively. These percentages are somewhat similar, for example, to those obtained in adjacent Westchester County and in the City of Baltimore. In the former during the 10 years 1950-1959, of the 69 pedestrians 18 years of age or older fatally injured and dying within 4 hours 64 were tested postmortem for alcohol. In this group the corresponding percentages were 42 per cent (27/64), 38 per cent (24/64), and 25 per cent (16/64).[29] In Baltimore from January, 1951, through April, 1956, 200 pedestrians 20 years of age and older were killed. Among these the percentages at or above 50 and 150 mg. per cent were, respectively, 45 per cent (90/200) and 32 per cent (64/200).[4] These data show that the appreciable prior consumption of beverage alcohol by adult pedestrians fatally injured by motor vehicles is a phenomenon by no means unique to Manhattan, and that the frequencies with which given blood alcohol concentrations are observed are remarkably similar elsewhere.

The high percentages of fatally injured Manhattan pedestrians showing high blood alcohol concentrations should not, however, be taken as typical of all adult Manhattan pedestrians. The control series represents the adult pedestrian traffic of the same sex composition as a case series derived largely in the evening and nighttime from accident sites at many of which elevated blood alcohol concentrations would be expected to be commonly found. Despite this it is noteworthy that 67 per cent (118/177) (Table XI) of the controls' breath specimens did not have measurable concentrations of alcohol (00), and that an additional 17 per cent (30/177) represented blood concentrations (10-40) in which many social drinkers would be expected to fall. It is of interest that the percentages of the control group with given concentrations were considerably higher than those obtained by Holcomb[17,19] and Lucas and associates[17] in their large series of drivers (see above, "Methods"). In the first of these, in which drivers were stopped in Evanston, Illinois, throughout the 24 hours, those having concentrations at or above 70 (sic), 110 (sic), and 150 mg. per cent, respectively, were 4.5 per cent (79/1,750), 1.3 per cent (23/1,750), and 0.4 per cent (7/1,750).[17,19] In the second investigation, in Toronto, Canada, in which drivers were stopped in the evening at accident sites, the percentages above 50, 100, and 150 mg. per cent were 8.7 per cent (176/2,015), 3.3 per cent (67/2,015), and 1.4 per cent (28/2,015), respectively.[17] These differences suggest that the frequencies of given blood alcohol

*U.S. "80 proof" equals "70 proof" under the definition employed in Canada and Great Britain. The difference between the British ounce (28.4 ml.) and the U.S. ounce (29.6 ml.) is negligible in this context.[15]

elevations may be higher in pedestrian than in driving populations, but this cannot be resolved until parallel studies of both such populations have been completed in the same geographic area. Such work is now under way in New York City.

It is pertinent in view of the age-associated risks of involvement and of fatal outcome, once involved, that *in the control group* those whose blood was estimated not to contain measurable quantities of alcohol (00) were significantly ($P < 0.05$) *younger* than those with measurable concentrations (10+ mg. per cent). The difference (40.3 vs. 41.9 years), however, was small. Further, those with low concentrations (10-40) in the control group (mean age 42.2) were not significantly ($P > 0.05$) different in age from those with higher concentrations (50+) (mean age 41.6).*

In the case group, in marked contrast, although the numbers were much smaller, those in the 00 group were significantly ($P < 0.05$) *older* (mean age 70.8 years) both than those in the 10-40 group (mean age 51.6 years) and than those in the entire 10+ group (mean age 46.2). The difference between the mean ages of the 5 members of the 10-40 group (see above) and the 9 members of the 50+ group (mean age 43.2), though suggestive, was not significant ($P > 0.05$).

As noted in connection with Table V, the members of the total case group were very significantly older than the members of the total control group. When comparisons were made between those cases and controls with given blood alcohol concentrations, the cases in the 00 and in the 10-40 mg. per cent groups, respectively, were both significantly older ($P < 0.05$) than the corresponding controls, but the difference between the mean ages in the case (43.2) and control (41.6) groups in the 50+ range was not significant ($P > 0.05$). These and the foregoing data show that in the series studied increased age was significantly associated with fatal pedestrian accident involvement, both in the absence of measurable prior ingestion of alcohol and in the case of those whose blood alcohol concentrations were relatively low (10-40). Similarly, relatively high blood alcohol concentrations were found to be significantly associated with such fatal accident involvement in the absence of significant differences in age (see above), a result also obtained when age (and sex) were controlled (Table XI*C*). These findings and inspection of the data suggest that the case series was comprised of two substantially discrete groups each of which had an increased risk of fatal involvement, namely, a group of the elderly whose blood either contained no measureable amounts of alcohol, or relatively little, and a group of the middle-aged who had been drinking heavily. Consequently, the design of control measures should take these characteristics into consideration. For example, as Schmidt and Smart[31] have appropriately pointed out, "highway education slogans" would not be expected to be efficacious in the case of accidents associated with alcoholism.

It would be of interest if it had been possible to determine the extent to which chronic alcoholics were overrepresented in the case series. Unfortunately, although at least a few of those killed are believed to have been alcoholic derelicts, it was not possible to investigate this point further. In addition, liver specimens

*The significance of the differences given in this and the following two paragraphs were calculated by the method of Scheffé for judging all contrasts in the analysis of variance.[30]

were not retained, and it was consequently not possible to describe the presence of fatty degeneration and cirrhosis among those killed, and, if found, to determine whether, as might be anticipated, blood alcohol concentration at death would have correlated with the presence of such hepatic disease. That such questions are of pertinence was demonstrated by excellent research in Sweden which showed that chronic alcoholics and other alcohol abusers were many times more often found among a consecutive series of male traffic accident victims than would have been expected on the basis of their numbers in the general population.[32] Similarly, Schmidt and Smart, studying an alcoholism clinic population in Toronto, have found that male chronic alcoholics who were drivers had motor vehicle accident rates per mile of exposure very significantly higher than expected in the general population. In the Swedish and Canadian series there was no overrepresentation of such heavy alcohol users in accidents in which alcohol was not a factor, and Schmidt and Smart have concluded with respect to such drivers "that the reported differences in accident involvement between alcoholics and the general driving population is closely related to the driving behavior only after the consumption of alcohol."[31] Whether this results exclusively from the pharmacologic effects of alcohol per se or whether other factors intimately associated with its use also contribute remains to be determined. This area will require much more work before these points can be entirely decided. On the basis of the evidence available from these other investigations and the present, descriptive evidence, it is reasonable to regard the chronic alcoholic as contributing both as a driver and as a pedestrian to the motor vehicle accident picture, but to an extent which requires further documentation. There can be no question, however, that motor vehicle accidents in general represent in part one source of the morbidity and mortality derivative from the excessive use of alcoholic beverages. Similarly, the accidents involving the elderly group showing little or no alcohol at death may be regarded as representing one source of the morbidity and mortality associated with advanced age, and as such should concern those in geriatric medicine.

The point has been made by others that few fatally injured pedestrians are the holders of licenses to drive motor vehicles.[21] This, however, is to be expected from the age distribution of those involved. On the basis of age- and sex-specific license-holding rates for New York City residents calculated from data available to the authors, only 11.9 license holders would have been expected in a 44 member group with the age and sex composition of the 44 known New York City residents in the case series (Table VII). Low percentages of license holders in such groups are, as a result, hardly surprising even though they may be of importance in choosing the emphasis of education and other control measures. Further, license-holding rates of pedestrians would be expected, because of the presumably disproportionate inclusion of nondrivers, to be lower than those of the general public of the same age and sex composition. In the present case it was possible to check this expectation by having the New York State motor vehicle license files manually checked for the 44 city residents of known name and address in the index case series. Three of these were found to have held licenses at death, and an additional 3 whose names, ages, and addresses were in part similar to those on

record in the files *may* have held licenses. The probability of observing this difference (6 vs. 11.9) by chance is < 0.05 (χ^2). However, because of the shortcomings of the state records as collected and maintained, this latter finding should be accepted with reservation pending confirmation.

Although the data available relative to the involved vehicles and drivers do not justify precise statistical analysis, it is pertinent that some of the pedestrians killed are known to have been *not* substantially responsible for the accidents in which they were involved. As examples: In one accident a motor scooter first involved in a nearby collision with a truck, threw its rider to his death and then approached and fatally injured a pedestrian. In another, one of the small number which occurred in the major business areas of the city, the operator of a sports car lost control of his vehicle and struck and fatally injured a pedestrian. Additional accidents, in which the pedestrians may not have been completely responsible, involved intoxicated drivers, and 4 accidents were "hit and run." In such cases the characteristics of the pedestrians killed would be expected to be more nearly those of the noninvolved pedestrians than would be the case among those presumably responsible in larger part for their own accident involvements. Consequently, since the case series includes some such cases, the associations found may be considered as conservative estimates of the magnitude of the associations which would probably have been found had it been possible to study only those totally responsible for their own deaths.

Similarly, the fatally injured group probably contained some individuals who were killed by forces of such great magnitude that anyone, regardless of age, would have been killed. The characteristics of such fatally injured individuals, granted their accident involvement, would not be influenced by an increased susceptibility to fatal outcome of pertinence in the case of lesser impacts, and as a result their characteristics would be expected to approach those of the relatively much larger nonfatally injured accident-involved group. Since those hit by such great forces would tend to be killed outright or, if not, to have relatively short survival, the effect of the inclusion of this group in the total case series would be expected to have most greatly influenced the characteristics of the subgroup comprised of those dead on arrival or dying within one hour.

Consistent with this expectation is the fact that the mean age of the dead on arrival and < 1 hour group, 48.2 years, was not significantly different from that, 48.4, of the nonfatally injured controls (see Tables III and V). In addition, this dead on arrival and < 1 hour group was significantly ($P < 0.05$) younger than the remainder of the fatally injured group. There was no significant age difference ($P > 0.05$), however, between those in the 1 to 3 hour and 4 to 71 hour groups; whereas those surviving 72 hours or longer were significantly ($P < 0.05$) older (mean age 70.4) than those dying between 1 and 71 hours (mean age 56.6) after their accidents. The latter finding is consistent with much clinical evidence as to the poorer course and increased occurrence of fatal, late complications among older patients.*

*The significance of the differences in this paragraph were calculated by the method of Scheffé for judging all contrasts in the analysis of variance.[80]

Finally, as in any investigation concerned with the pathology derivative from a given population, questions must arise as to the extent to which the sequences of events leading to that pathology are qualitatively and quantitatively similar to those operative in other populations. Although, as Russell[33] has pointed out, any event or group of events must be totally unique if described completely in all parameters, findings based upon one population tend to have relevance elsewhere to the extent to which the pertinent characteristics of the one are elsewhere present. Since the subpopulations constituting the Manhattan community are in many respects unique, the question must arise as to the extent to which the results reported here would be duplicated if other populations were studied. Unfortunately, since this is the first investigation of its kind, it is at present not possible to compare its findings definitively with those from other areas. It is possible, however, to point out certain similarities between the Manhattan situation and that obtaining elsewhere.

First, as noted in the introduction, the distribution of the age-specific death rates of pedestrians killed nationally in the United States is J-shaped with a maximum in the grade school and preschool years; a minimum in the late second, third, and early fourth decades; and a progressively increasing rate thereafter. From data available to the authors it has been found that the distribution of the age-specific pedestrian death rates of Manhattan residents of all ages is similarly J-shaped and that the rates in corresponding age groups are of similar magnitude. Second, it has been noted, as reported for other cities, that the accidents studied tended to occur outside of the major business areas. Third, the time-of-day distribution is similar to that seen elsewhere. And, fourth, as elsewhere, a substantial fraction of those fatally injured had been drinking heavily. These similarities between the Manhattan situation and that in other areas suggest that the factors shown here to be of importance in Manhattan are not completely without relevance in other areas.

SUMMARY

1. The present investigation, the first of its kind, was designed to compare the characteristics of pedestrians 18 years of age and older fatally injured in Manhattan with those who though similarly exposed were not similarly involved. The case series consisted of 50 of the 52 such pedestrians fatally injured at known sites and times in Manhattan between May 3 and Nov. 7, 1959, and whose deaths occurred during the same period. Autopsies were performed in all cases and appropriate specimens obtained. Data with respect to those nonfatally injured were also secured.

2. The control group was obtained by visiting each accident site on a subsequent date, but on the same day of the week and at exactly the same time of day, and stopping, interviewing, and obtaining breath specimens (for alcohol) from the first 4 pedestrians of the same sex as the deceased, and 18 years of age or older. Of 212 so stopped, only 12 failed to cooperate fully.

3. The results obtained included both purely descriptive and controlled observations. Among the former: The accidents tended to occur outside of major

shopping and business areas. Fifty-one per cent occurred in the 6 hours preceding midnight, 73 per cent in the 12 hours beginning at 3 P.M., and the smallest number in the 3 hours ending at 9 A. M. Forty-four per cent of those killed survived less than 6 hours. This together with the common evening and nighttime occurrence underscores the need for emphasizing the same period in the organization of emergency medical care.

4. Weather, raining vs. not raining, was not significantly associated with the occurrence of such accidents, although increased risk with rain may have been obscured by associated decreases in pedestrian density.

5. The mean age of those killed was 58.8 years; of those nonfatally injured 48.4 years; and of those interviewed at the fatal accident sites 41.6 years. The most reasonable interpretation of these findings is that there is, first, an age-associated risk of involvement per se, and, second, an age-associated risk of fatal outcome, once involved. Because of these differences and the probability that others of the characteristics studied would show associations with age, comparisons between the case and control groups included comparisons between age- and sex-matched members of both groups.

6. The members of the case group were significantly more often foreign born, less often married, and more often of lower socioeconomic status than were those in the control group. However, when these comparisons were made between cases and controls of the same age and sex, no significant differences remained. It was also found that neither Negroes nor those born in Puerto Rico, two major population groups, were significantly more or less commonly found in the case than in the control groups.

7. Only 4 of the 46 persons in the case group of known residence lived outside of Manhattan. Consequently, neither commuters nor visitors contributed substantially to the deaths studied. In addition, many of those killed were hit within relatively short distances of their residences. This can *not* be attributed entirely to a corresponding localization of exposure since Manhattan residents were found significantly more often in the case series than among those similarly exposed *at the same sites*, even when the difference in age between the two groups was taken into consideration.

8. Because postmortem specimens for alcohol analysis were employed, comparisons involving the blood alcohol concentrations of members of the case series were limited to those who had survived less than 6 hours. In this group 26 per cent showed no alcohol, 47 per cent had concentrations of 50 mg. per cent or higher, 42 per cent, 100 mg. per cent or higher, and 32 per cent, 150 mg. per cent or higher. The corresponding percentages in the much larger control group were 67 per cent (none), 16 per cent ($\leq$ 50), 8 per cent ($\leq$ 100), 6 per cent ($\leq$ 150 mg. per cent), respectively. Significant differences were found whether the cases were compared with the members of the total control group, with the site-matched controls from the same accident sites, or with age- and sex-matched members of the control group. The data suggest that the risk first becomes significantly increased in the low, 10-40 mg. per cent range.

9. The members of the case group found to have either low blood alcohol concentrations or no measurable amount were significantly older than the cor-

responding members of the control group. In contrast, the members of the case group with high blood alcohol concentrations were not significantly older than the corresponding members of the control group. The data suggest that the case series was composed of two substantially discrete groups, each with increased risk, namely, a group of the elderly who had been drinking little or not at all, and a group of the middle aged who had been drinking heavily.

10. The importance of determining the extent to which the chronic alcoholic is overrepresented in such accidents is discussed. It is believed that such individuals were present in the case series, but controlled observations appropriate to this point were not possible. It is emphasized that fatal adult pedestrian accidents must be regarded as contributing portions of the morbidity and mortality associated with alcoholism and with advanced age.

This work would not have been possible without the superb cooperation of the New York City Police Department, Stephen P. Kennedy, Commissioner, and, in particular, of the officers and men of its excellent Accident Investigation Squad, Lieutenant Hugh A. Cleary, Commanding Officer. The authors also are indebted to Captain H. E. Finney, Director, New York City Police Laboratory, for his kind loan of equipment and supplies, and to Dr. Milton Helpern, Chief Medical Examiner, City of New York, and his staff for their continued cooperation.

In addition, Theodore V. Boroian, Martin F. McKneally, John J. Kuiper, and John M. Weatherly, all of Cornell University Medical College, carried a large share of the burden posed by the often inconvenient site visits, and this together with the high level of professional competence with which they worked are greatly appreciated. The authors also wish to thank Dr. Lorenzo Galante for performing the many blood and tissue analyses, Dr. Alan Gittelsohn, Mrs. Sandra H. Kinch, and Miss Elizabeth Parkhurst for their assistance with the evaluation of the data, and the staffs of the Driver Research Center and Division of Epidemiologic Research for their continued support.

The Breathalyzer used was made available through the generous cooperation of its developer, Professor Robert F. Borkenstein, Indiana University, and Mr. William H. Stephenson, Stephenson Corporation, Red Bank, New Jersey. The Saran bags, among the first produced, were obtained through the courtesy of The Central Scientific Company of Canada; Professor G. H. W. Lucas, University of Toronto, and the Ontario Attorney-General's Laboratory, Toronto.

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84 Holland Ave., Albany, N. Y. (Dr. Haddon)
1300 York Ave., New York, N. Y. (Dr. McCarroll)

NO HITS, NO RUNS, TWO ERRATA

In a book review on page 377 of the September, 1961, issue, a typographical error transformed a mild pun into confusing inanity. After a quotation from Dr. Platt which ended ". . . biologically you are nothing but a lot of clones," this reviewer had added: [One wonders whether Platt thinks of his friends as old *clonies*.]. Some well-intentioned person "corrected" *clonies* to *cronies*, and the point was lost.

This error is as nothing, however, compared to the typographical horror in the introduction to a symposium on pain organized for the July, 1956, issue of this Journal. There I had made the observation that "It is perhaps worth *noting* that four of our ten participants are anesthetists." This ended up as: "It is worth *nothing* that four of our ten participants are anesthetists."

Louis Lasagna

Book Reviews

REHABILITATION AND WORLD PEACE. Proceedings of the Eighth World Congress of the International Society for the Welfare of Cripples, Eugene J. Taylor, Editor. New York, 1960, International Society for Rehabilitation of Disabled, 701 First Avenue. Pp. 433, not indexed. Price $2.00.

At its eighth World Congress in 1960, the International Society for the Welfare of Cripples changed its name to the International Society for the Rehabilitation of the Disabled. This change dramatizes the Society's determination to emphasize the dynamic nature of treatment of the disabled, an expression of its goal to bring every disabled person to his maximal medical, physical, emotional, and vocational potential.

Medical rehabilitation has a number of special techniques which it uses in the treatment of patients, such as physical medicine, the team approach, and community facilities. Rehabilitation is, however, also a movement or attitude, and we find euphoria and religious zeal associated with its apostles. The principal theme of the conference is that medical rehabilitation throughout the world brings understanding between peoples which will help overcome national differences. "This is the message of rehabilitation—your life in others. This is the message of this congress. This is the formula for world peace." (p. 421.) What other international congress has ended with silent prayer? (p. 422.)

No doubt enthusiasm is an important feature in overcoming the hopeless acceptance of chronic disability, particularly since we know that a great many patients who could be helped are languishing in various institutions and at home. Furthermore, successful rehabilitation requires the participation, not only of a large number of laymen, but also of government organizations. It is only with high purposes and enthusiastic leadership that such participation can be mobilized.

For people trying to understand the place of the volunteer health organization in society, this book will help supply the answer. It outlines specific needs of the disabled in various countries throughout the world; it suggests methods of fulfilling these needs through community action, government participation, and the use of volunteers. This book is recommended particularly to physicians dealing with chronic diseases, to all trustees, directors, or workers in various volunteer health organizations, and indeed to anyone who makes a contribution to such an organization.

Douglas Carroll

MANAGEMENT OF HYPERTENSIVE DISEASE. By Joseph C. Edwards, M.D. With a foreword by Paul Dudley White, M.D. St. Louis, 1960, The C. V. Mosby Company. Pp. 360, indexed. Price $15.00.

Management of Hypertensive Disease in the course of 360 pages of text gives an almost encyclopedic review of the many treatments which confuse and confound the present-day management of hypertension. Its best section is one containing 1,622 references which emphasizes the disproportionate amount of study and thought which has gone into this problem and the few substantial gains made.

Monolithic authorship of this type of textbook has become a rarity, and such attempts tend to fall between the extremes of egotistically expressing nothing but one's own views, prejudices, and conclusions, and the ultimate comprehensive bird's-eye view of all and every shade of opinion, which cannot but leave the reviewer exhausted, tired, and confused. As an example of the latter extreme, in Chapter 6 when reasons for drug therapy are discussed, the author follows his proposal of the necessity to lower the blood pressure in essential hypertension by six references which seem to confirm this, and only a paragraph later quotes another eleven references which appear to point in the opposite direction. Riding on the fence may be a pleasurable exercise, but the author has failed to integrate the many papers quoted with his own views into a comprehensible vade mecum. Moreover, the surfeit of scantily quoted work does not add to the value of this book. It would have been far wiser to have fewer references on each major point intelligently discussed and woven together into the fabric that the author desires to give us.

There are many good sections in this book also and of particular interest are the excellent

case which the author quotes to make his points. In almost all cases where race is mentioned, Dr. Edwards' patients are white. The relative lack of attention given in the book to the serious side effects of hypotensive therapy, such as progressive renal failure and renal shutdown, as well as cerebral edema, suggests that there must be a striking difference between the response of white hypertensive patients in St. Louis and the Negro hypertensive population of Baltimore, which so often shows deterioration on treatment, in the experience of this reviewer. This constitutes another question mark in a field which already suffers no lack of them.

Frederick W. Wolff

CHEMOBIODYNAMICS AND DRUG DESIGN. By F. W. Schueler, Ph.D. New York, 1960, McGraw-Hill Book Company, Inc. Pp. 638, indexed. Price $19.50.

Ever since A. J. Clark wrote his classic monograph on the theoretic aspects of drug action, pharmacologists have been hoping for a new book which would represent a step forward in the formulation of fundamental concepts of pharmacologic action at the cellular level. With the announcement of Dr. Schueler's volume, many thought that this hope would be realized. Schueler is a bright young pharmacologist whose reputation rests on his work relating chemical structure to biologic activity.

Alas, this book is far from the mark. It is a verbose, rambling misch-masch of philosophy, statistics, chemistry—in fact, one gets the feeling that the author tried to put in everything he knows, or at least as much as the publishers would allow. The book is an undisciplined (and occasionally erroneous) exercise in writing which is not likely to be used as a text or supplementary text for any course in a university, medical school, or pharmacy school. (Nor will drug house chemists derive much help from it either.)

It's a great pity that Dr. Schueler didn't follow Clark's lead and write a *short* book, perhaps on the question of the rational search for new drugs of biologic interest. His friends will surely forgive him this one aberration if he promises not to foist any more pseudo-Hegelian syntheses on us poor struggling pharmacologists.

One last thought: What were the editors at McGraw-Hill doing when this book was being processed? Authors shouldn't be expected to be their own critics; ruthless slashing with a red pencil might have saved Dr. Schueler some bad notices.

Louis Lasagna

TOXICOLOGY: MECHANISMS AND ANALYTICAL METHODS. Vol. 1 and 2. Edited by C. P. Stewart and A. Stolman. New York, 1960 and 1961, Academic Press, Inc. Vol. 1, 774 pp., indexed. Price $22.00. Vol. 2, 921 pp., indexed. Price $25.00.

These two volumes will certainly find their way into many hospital and medical school libraries. They collate a vast amount of toxicologic data scattered widely through the world literature. The numerous contributors are experienced scientists and speak with authority (even if not always with accuracy). If drug poisonings intrude on your professional life with any frequency, you'd better have a look at these books.

Louis Lasagna

CARDIOVASCULAR ABSTRACTS I-1960. Selected from World Literature. Edited by Stanford Wessler, M.D. New York, 1961, The American Heart Association. Pp. 192, indexed.

This is a compilation of one year's worth of abstracting from *Circulation*. "It is an experiment, and its continuation as an annual monograph will depend upon the response of physicians." It does not pretend to be a comprehensive coverage of the world literature on cardiovascular research, but probably covers the field pretty well. One question is, however, whether physicians who already have these abstracts in their monthly issues of *Circulation* will want to subscribe to such an annual volume? My guess would be no. A suggestion: Why not eliminate the monthly abstracts from *Circulation* and publish an indexed volume of abstracts (or perhaps two) a year separately, perhaps as part of the subscription to *Circulation?*

Louis Lasagna

EPIDEMIOLOGIC METHODS. By Brian MacMahon, M.D., Ph.D., D.P.H., Thomas F. Pugh, M.D., M.P.H., and Johannes Ipsen, C. M., Dr. Med., M.P.H. Boston and Toronto, 1960, Little, Brown & Company. Pp. 302, indexed. Price $7.50.

The traditional method of exposition of epidemiology in textbooks and the classroom has been by a review of the epidemiologic aspects of a series of specific diseases. From such a series it was hoped that the student and/or reader would be able to extract the principles and methods used by the epidemiologist in approaching a disease problem. In view of the broadened scope of the concepts and applications of the epidemiologic approach in the past 10 to 15 years, there has been a long-felt need for a unified treatment of epidemiologic methods and reasoning. The authors have provided for such a need, at an introductory level.

The first half of the book is devoted to general discussions on the role of epidemiology, concepts of disease causation, problems in the classification of illness, statistical indices of disease measurement, sources of data, and the general strategy of epidemiology. In the next third, the authors individually consider the variables of interest to the epidemiologist; thus, separate chapters are devoted to age, sex and ethnic groups, time, place, etc. The remainder of the book deals with cohort studies, case history studies, and experimental epidemiology.

The mode of presentation and discussion of the epidemiologic variables is of interest; it can be exemplified by the treatment of ethnic group. First, the different concepts of an ethnic group, such as race, nationality, and religion, are discussed and illustrative data are presented. A section is then devoted to "Interpretation" where consideration is given to the various kinds of inferences that may be derived from the observation of a differential frequency of a disease in different groups. Thus the reader is placed in the position of the epidemiologist who has observed a relationship and then tries to think through the meaning of the observations.

The interpretations of some of the data presented by the authors are not necessarily exhaustive and the reader may find himself, as this reviewer did, disagreeing with several of them. For example, the authors present data on the point prevalence of patients in mental hospitals by marital status in the United States and note that there is a higher prevalence among the widowed than among married persons. They feel that "the most likely explanation of this relationship is that the stress of bereavement or of widowhood has a causal relationship to the manifestation of mental disorder" and emphasize that this observation is difficult to explain on the basis of selection. Apparently, they have not taken into account such possible explanations as, (1) that widows who are mentally ill probably have a lower probability of remarrying than do those who are not and (2) the changes in social and living conditions resulting from widowhood may be the important causal factor rather than emotional stress. This comment should not be taken critically since differences of opinion with respect to the interpretation of observations are bound to develop.

This reviewer was surprised to find the omission of several important areas of epidemiologic investigation. For example, there is no over-all discussion of familial aggregation of disease. The chapter on experimental epidemiology is limited to trials in human populations although this term has been used in the past to include the investigation of experimental epidemics among laboratory animals. Also, there is no discussion of epidemic theory, an area that has been of interest to many epidemiologists. The usefulness of this volume as a text would be increased by the inclusion of these subjects.

This volume is of real value as a text in introductory courses in epidemiology and will be useful to medical and public health students and all others who are interested in epidemiologic methods in the study of disease. The authors and publishers are to be commended on the overall clarity of presentation of both the textual and illustrative material.

Abraham M. Lilienfeld

SCIENCE AND HUMAN VALUES. By J. Bronowski, Ph.D. London, 1961, Hutchinson & Co., Ltd. Pp. 96, unindexed, with notes. Price 12s, 6d.

Bronowski is one of the great literary stylists among scientists writing for the lay public. His background is reminiscent of Conrad: he is a Pole-become-Englishman. Equally at home with the poems of William Blake or mathematics, Bronowski has turned out an extraordinary group of publications, of which the most recent have been *The Face of Violence* (a prize-winning radio play

plus an even better essay on the same subject) and *The Western Intellectual Tradition*, a delightful and refreshing look at history, written in collaboration with Bruce Mazlish of M.I.T.

Science and Human Values is a collection of three essays plus some absorbing footnotes. (The titles: "The Creative Mind," "The Habit of Truth," and "The Sense of Human Dignity.") If you've never sampled Bronowski, start at once with this wise little book. If you know Bronowski already, you don't need any prompting.

Louis Lasagna

STATISTICS. A NEW APPROACH. By W. Allen Wallis and Harry V. Roberts. Glencoe, 1956, The Free Press. Pp. 646, indexed. Price $7.00.

Statistics: A New Approach is perhaps the finest book available for people who wish to grasp the fundamental principles of statistics without necessarily mastering mathematical theory or a large number of specific techniques There *are* some chapters dealing with specific techniques, but the unique value of the book is its readable style and superbly chosen examples of the fundamentals. The few pages on the regression fallacy, for instance, are superb. The examples from various fields are well chosen, and some are strokes of genius (like picking the ignored Pearl Harbor radar signals to illustrate the hazards of disregarding "incredible" extreme values). Surely this book must be classed as one of the great textbooks.

Louis Lasagna

HOME CARE. Hospital Monograph Series #9. By David Littauer, M.D., I. Jerome Flance, M.D., and Albert F. Wessen, Ph.D. Chicago, 1961, American Hospital Association. Pp. 110, not indexed. Price $2.75.

Home Care is a typical monograph of the American Hospital Association. It is well organized and comprehensive. It brings together a lot of materials from a variety of home-care programs. The only thing comparable to this is one six years old, "A Study of Selected Home Care Programs," Public Health Monograph No. 35, United States Government Printing Office, 1955.

Special attention is given to the program of the Jewish Hospital of St. Louis, which is modeled after the pioneering Home Care Program of the Montefiore Hospital of New York City. Of particular interest in this monograph are some of the obstacles which have prevented home care from assuming as significant a role in the care of the chronically sick as it merits.

This is a useful monograph for those planning the development of home-care programs.

Martin Cherkasky

RADIATION PROTECTION AND RECOVERY. Edited by A. Hollaender. New York, 1960 Pergamon Press, Ltd. Pp. 392, indexed. Price $10.00.

This volume, edited by Dr. Alexander Hollaender, the head of the Biology Division of the Oak Ridge National Laboratory, concerns itself with the multiple aspects of protection and recovery from radiation-induced injury at all levels of biologic organization. Thus, one will find discussion of such topics as protection of macromolecules in vitro, chemical protection to mammals, protection in fungi and bacteria, chromosome aberrations, and modification of delayed somatic effects of ionizing radiation in mammals.

The book, on the whole, successfully integrates the observed effects of radiation injury and the attendant theories with the effects of protective agents to provide a better insight into the probable mechanisms of action of various chemical, physical, and biologic agents. Although this book concerns itself primarily with ionizing radiation, pertinent information regarding ultraviolet radiation and photoreactivation is included.

Current research in this area is very active; nevertheless, this volume is relatively up to date and provides a valuable conceptual and factual summary of this interesting aspect of radiobiology. This book is not intended for the biologist or physician who has but casual interest in radiobiology. It is, however, recommended as informative reading to the radiobiologist and those biologists and physicians who have the interest and some fundamental knowledge of radiobiology.

George W. Santos

Announcements

The International Society for Rehabilitation of the Disabled has announced the availability of its new publication in the field of special education entitled WORLD FRONTIERS IN SPECIAL EDUCATION.

Especially planned for those persons active in the field of special education, the publication is a record of the proceedings of the First International Seminar on Special Education held recently in West Point, New York. The event was sponsored by the World Committee on Special Education of the International Society in cooperation with the World Rehabilitation Fund, Inc., with the aid of a grant from Lilly Endowment, Inc.

The lectures, covering various topics including philosophy, administration, personnel, counseling, and guidance, would be of interest to all those active in the teaching profession and in the field of Special Education.

World Frontiers in Special Education, with an introduction by Howard A. Rusk, M.D., consists of 50 pages and costs $1 per copy. Copies may be ordered directly from the International Society for Rehabilitation of the Disabled, 701 First Avenue, New York 17, N. Y.

Three annual PUBLICATIONS OF THE CENTER FOR AGING RESEARCH, Division of General Medical Sciences, Institutes of Health, are now available for distribution. These are: *Research Highlights in Aging, 1960; Activities of the National Institutes of Health in the Field of Gerontology, January, 1961;* and *Research Programs in Aging, 1960.*

Research Highlights in Aging presents a review of a selected number of scientific papers on research in aging carried out or supported by the National Institutes of Health. The articles reviewed range from fundamental studies in the biology of aging to studies concerned with the physical, psychological, and social problems of aging people. In addition to the scientific papers presented, the brochure also includes reviews of new literature in the field, meetings of considerable importance, programs of the five major multidisciplinary centers for aging research, and training programs.

Activities of the National Institutes of Health in the Field of Gerontology lists all grants for research on aging active on Jan. 31, 1961. The grants are arranged in two categories—those primarily related to aging and those secondarily related to aging. In each category the grants are classified as follows: General, Major Multidisciplinary Research Projects, Structural Aspects of Aging, Physiological and Biochemical Aspects of Aging, Psychological Aspects of Aging, Social Aspects of Aging, Identifiable Disease Processes, and Training.

The third document, *Research Programs in Aging*, prepared originally as background material for submission at Congressional hearings on appropriations, covers all intramural and extramural studies supported or conducted by the National Institutes of Health in the field of gerontology.

At the conclusion of the narrative report in this document, comparative statistical summaries are given showing the number of grants and cost of these grants for a four-year period.

The final section in *Research Programs in Aging* is a bibliography listing papers presented and published during calendar year 1960 by members of the following staffs: Gerontology Branch, National Heart Institute; Section on Aging, National Institute of Mental Health; Duke University; the Albert Einstein College of Medicine; and the Center for Aging Research.

All documents are available free upon request to the Information Officer, Center for Aging Research, National Institutes of Health, Bethesda 14, Md.

Important Notice to Readers

CHANGE OF PUBLISHER

An agreement has been made between The C. V. Mosby Company and Pergamon Press Incorporated, whereby Pergamon Press will publish the JOURNAL OF CHRONIC DISEASES starting with the January, 1962, issue.

All orders and subscription correspondence should, in the future, be addressed to Pergamon Press Inc., 122 East 55th Street, New York 22, N.Y.

An announcement concerning the enlarged scope and broader international coverage of the JOURNAL will be made by the Editors in the January issue.

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